

STATUS OF REFORMS TO EPA'S INTEGRATED RISK INFORMATION SYSTEM

JOINT HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT &
SUBCOMMITTEE ON ENVIRONMENT

COMMITTEE ON SCIENCE, SPACE, AND
TECHNOLOGY

HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

SECOND SESSION

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STATUS OF REFORMS TO EPA'S INTEGRATED RISK INFORMATION SYSTEM

WEDNESDAY, JULY 16, 2014

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND SUBCOMMITTEE ON
ENVIRONMENT,
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY,
Washington, D.C.

The Subcommittees met, pursuant to call, at 1:32 p.m., in Room 2318 of the Rayburn House Office Building, Hon. Paul Broun [Chairman of the Subcommittee on Oversight] presiding.

LAMAR S. SMITH, Texas
CHAIRMAN

EDDIE BERNICE JOHNSON, Texas
RANKING MEMBER

Congress of the United States
House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

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Status of Reforms to EPA's Integrated Risk Information System

Wednesday, July 16, 2014

2:00 p.m. to 4:00 p.m.

2318 Rayburn House Office Building

Witnesses

Dr. David Dorman, Member, Committee to Review EPA's IRIS Process, National Research Council

Dr. Kenneth Olden, Director, National Center for Environmental Assessment,
U.S. Environmental Protection Agency

Ms. Rena Steinzor, Professor of Law, University of Maryland; President, Center
for Progressive Reform

Mr. Michael P. Walls, Vice President of Regulatory and Technical Affairs,
American Chemistry Council

U.S. House of Representatives
Committee on Science, Space, and Technology
Subcommittee on Oversight
Subcommittee on Environment

HEARING CHARTER

Status of Reforms to EPA's Integrated Risk Information System

Wednesday, July 16, 2014
2:00 p.m. – 4:00 p.m.
2318 Rayburn House Office Building

Purpose

On Wednesday, July 16, 2014, the Subcommittees on Oversight and Environment will hold a joint hearing entitled *Status of Reforms to EPA's Integrated Risk Information System*.

In May, the National Research Council (NRC) released a report, *Review of EPA's Integrated Risk Information System (IRIS) Process*.¹ This report is a follow-up assessment of how EPA is implementing recommendations from an NRC review published in April 2011 on EPA's formaldehyde assessment.² In the 2011 report, the NRC "strongly faulted EPA's methodology in crafting its draft assessment, warning of a pattern of problems in how the agency crafts assessments for its Integrated Risk Information System (IRIS) database that could continue to hamper future risk studies."³ Chapter 7 of the 2011 NRC report detailed the deficiencies in EPA's formaldehyde assessment as well as shortcomings with the agency's overall IRIS assessment methods.

This hearing will examine EPA's actions in response to both NRC reports in order to evaluate the status of the agency's reforms to the IRIS program. The Science, Space, and Technology Committee has held several hearings on this program, with the most recent one in 2011.⁴ Initially, these hearings focused on the IRIS interagency review process, and delved into the role of the White House and other agencies to determine the extent of their involvement in IRIS' chemical risk assessments. The focus of the most recent hearings, including this hearing, has shifted to reviewing the efficacy of EPA's overall IRIS process.

¹ NRC Report, "Review of EPA's Integrated Risk Information System (IRIS) Process," May 6, 2014, available at: http://www.nap.edu/catalog.php?record_id=18764; hereinafter NRC 2014 IRIS Report.

² NRC Report, "Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde," April 8, 2011, available at: http://www.nap.edu/catalog.php?record_id=13142; hereinafter NRC 2011 Formaldehyde Report.

³ Maria Hegstad, "NAS Sets Back EPA Proposal For Strict Formaldehyde Risk Assessment," Environmental NewsStand, April 8, 2011, available at: <http://insideepa.com/Superfund-Report/Superfund-Report-04/18/2011/nas-sets-back-epa-proposal-for-strict-formaldehyde-risk-assessment/menu-id-1094.html>.

⁴ Subcommittee on Investigations & Oversight Hearing, "EPA's IRIS Program: Evaluating the Science and Process Behind Chemical Risk Assessment," July 14, 2011, available at: <http://science.house.gov/hearing/investigations-and-oversight-hearing-epas-iris-program>.

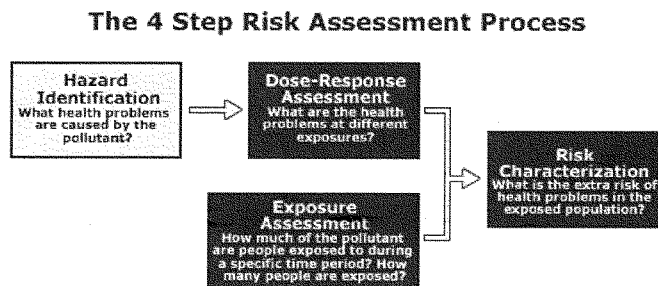
Witnesses

- **Dr. David Dorman**, Member, Committee to Review EPA's IRIS Process, National Research Council
- **Dr. Kenneth Olden**, Director, National Center for Environmental Assessment, U.S. Environmental Protection Agency
- **Ms. Rena Steinzor**, Professor of Law, University of Maryland; President, Center for Progressive Reform
- **Mr. Michael P. Walls**, Vice President of Regulatory and Technical Affairs, American Chemistry Council

Background

IRIS was established in the 1980s as an internal EPA database to provide a single source of information on the risks associated with exposure to chemicals. The IRIS database provides hazard identifications and dose-response assessments of chemicals that cover cancer and non-cancer outcomes. Examples of potential non-cancer health effects addressed in IRIS assessments include effects on the immune system, the reproductive system, the nervous system and the endocrine system. Hazard identifications and dose-response assessments are two of the four components that allow regulatory agencies to produce risk assessments, with the other two components being exposure assessment and risk characterization. The National Academy of Sciences defines risk assessments as "the characterization of the potential adverse health effects of human exposure to environmental hazards."⁵ Figure 1 further elaborates on the four-step risk assessment process.

Figure 1



Source: EPA website, available [here](#).

⁵ NRC Report, "Risk Assessment in the Federal Government: Managing the Progress," 1983, available at: http://www.nap.edu/catalog.php?record_id=366.

Historically, entries to the IRIS database were the result of extensive in-house development by the science staff at EPA, peer review processes with experts from outside the agency, and opportunities for public input and comment. However, as IRIS grew and gained more influence, EPA restructured the IRIS process which led to the end of other, previously successful collaborative platforms. EPA's restructuring ultimately led to several reorganizations of the IRIS process, but the quality of IRIS assessments continue to be an issue of concern.

In addition to the NRC report in 2011, the U.S. Government Accountability Office (GAO) also reviewed the IRIS program in March 2008. GAO reported that "the IRIS database was at serious risk of becoming obsolete because EPA had not been able to routinely complete timely, credible assessments. After subsequent reports, in January 2009 [GAO] added EPA's processes for assessing and controlling toxic chemicals to [its] list of areas at high risk for waste, fraud, abuse, and mismanagement or in need of broad-based transformation."⁶ EPA's IRIS program remains on GAO's High-Risk list.⁷

The IRIS program was originally created to ensure consistency solely within the EPA. However, "other federal agencies, various state and international agencies, and other organizations have come to rely on IRIS assessments for setting regulatory standards, establishing exposure guidelines, and estimating risks to exposed populations."⁸ The most recent GAO report on this matter also mentions the increasing importance of the program at EPA program offices and regions, local environmental programs, and international regulatory bodies. In addition, GAO highlights that "[a]lthough the information in the IRIS database is a critical primary component of EPA's capacity to support scientifically sound decisions, policies, and regulations, we have reported previously on EPA's difficulty producing timely, credible IRIS toxicity assessments."⁹

2011 NRC Report

In April 2011, the NRC published a study on EPA's draft formaldehyde IRIS assessment issued in 2010. In addition to providing recommendations specific to the formaldehyde assessment, the NRC also dedicated a chapter titled "A Roadmap for Revision" that offered suggestions regarding EPA's IRIS assessment process.¹⁰

In the summary of the report, the panel commented on the similarities in some of the problems with the IRIS assessment on formaldehyde, and those identified in other reports published by previous NRC committees:

⁶ David Trimble, GAO Director, Natural Resources and Environment, "Testimony before the Subcommittee on Investigations & Oversight, Committee on Science, Space, and Technology," July 14, 2011, available at: http://science.house.gov/sites/republicans.science.house.gov/files/documents/hearings/071411_Trimble.pdf

⁷ GAO Report to Congressional Committees, "High-Risk Series: An Update," February 2013, available at: <http://www.gao.gov/assets/660/652133.pdf>.

⁸ NRC 2014 IRIS Report, *supra*, note 1.

⁹ GAO Report to Senate Committee on Environment and Public Works, "Chemical Assessment: An Agencywide Strategy May Help EPA Address Unmet Needs for Integrated Risk Information System Assessment," May 2013, available at: <http://www.gao.gov/assets/660/654489.pdf>.

¹⁰ NRC 2011 Formaldehyde Report, *supra*, note 2.

“Overall, the committee noted some recurring methodologic problems in the draft IRIS assessment of formaldehyde. Many of the problems are similar to those which have been reported over the last decade by other NRC committees tasked with reviewing EPA’s IRIS assessments for other chemicals. Problems with clarity and transparency of the methods appear to be a repeating theme over the years, even though the documents appear to have grown considerably in length. In the roughly 1,000-page draft reviewed by the present committee, little beyond a brief introductory chapter could be found on the methods for conducting the assessment. Numerous EPA guidelines are cited, but their role in the preparation of the assessment is not clear. In general, the committee found that the draft was not prepared in a consistent fashion; it lacks clear links to an underlying conceptual framework; and it does not contain sufficient documentation on methods and criteria for identifying evidence from epidemiologic and experimental studies, for critically evaluating individual studies, for assessing the weight of evidence, and for selecting studies for derivation of the RfCs and unit risk estimates.”¹¹

2014 NRC Report

House Report 112-151¹² that accompanied the Consolidated Appropriations Act of 2012 (P.L. 112-74) directed EPA to adopt the recommendations from Chapter 7 of the NRC’s 2011 report into the IRIS program and contract with the NRC for a new report to review the agency’s implementation of those recommendations – leading to the review completed in May 2014.

While the 2014 NRC report describes EPA’s proposed changes as “substantial improvements,”¹³ it does offer “further guidance and recommendations to improve the overall scientific and technical performance of the program.”¹⁴ For example, according to the NRC press release accompanying the 2014 report:

“In response to the recommendations in the formaldehyde report, EPA developed a new document structure, added a standard preamble to all assessments that describes the IRIS process, drafted a handbook that provides a more detailed description of this process and its underlying principles, formed chemical assessment support teams to oversee the process and ensure consistency, and increased opportunities for stakeholder input.”¹⁵

¹¹ Ibid.

¹² House Report 112-151, Department of the Interior, Environment, and Related Agencies Appropriations Bill, 2012, available at: <http://www.gpo.gov/fdsys/pkg/CRPT-112hrpt151/pdf/CRPT-112hrpt151.pdf>.

¹³ NRC 2014 IRIS Report, *supra*, note 1.

¹⁴ NRC Press Release, “Substantial Improvements Made in EPA’s IRIS Program, Report Says,” May 6, 2014, available at: <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=18764>; hereinafter NRC 2014 IRIS Report Press Release.

¹⁵ Ibid.

The NRC press release also states that while the review committee considered the preamble useful, “it doesn’t fulfill the need for a description in each assessment that indicates how the general principles are applied. The report recommends that the handbook be peer-reviewed, that IRIS assessments clearly identify the members of all teams involved, and that outside experts be engaged when needed. It adds that EPA should provide technical assistance to stakeholders who might not have the resources to provide input into the IRIS process.”¹⁶

Under the leadership of Dr. Kenneth Olden with the EPA, who will testify at this hearing, there appears to be an effort by the agency to implement reforms to IRIS in response to the NRC recommendations and suggestions from the 2011 and 2014 reports. Dr. Olden previously served as the Director of the National Institute of Environmental Health Sciences from 1991 to 2005¹⁷ and was also a member of the Bipartisan Policy Center’s 2009 Science for Policy Project, which called for “greater transparency in analyzing the science behind policy making.”¹⁸ Dr. Olden’s background and position at EPA is encouraging news for transparency advocates for the IRIS program as well as at the agency in general.

EPA is still early in its reform of the IRIS process as there have been no IRIS assessments issued yet that reflect the NRC recommendations. According to the NRC’s 2014 report, questions still remain regarding the specifics and timing of EPA’s actions, examples of which include:¹⁹

- A major challenge for EPA in problem formulation is determining which adverse health outcomes should be evaluated in a specific IRIS assessment;
- EPA has implemented a standardized approach to evaluating evidence, and while it correctly identifies attributes that can be used to judge study quality, it does not describe how it plans to assess the risk of bias in the identified studies. NRC did not recommend any specific approach to assessing bias, but said that the approach chosen by EPA and its results should be fully described and reported in the IRIS assessment;
- After systematic review is completed, an IRIS assessment must combine all the individual lines of evidence to come to a judgment about whether a chemical is hazardous to human health, a process the committee referred to as “evidence integration.” EPA currently relies on a guided expert judgment process for evidence integration. EPA should either make this process more transparent if it chooses to continue using this approach or adopt a structured process for evidence integration;

¹⁶ Ibid.

¹⁷ Eddy Ball, “Olden Named to Head EPA Programs,” *Environmental Factor*, July 2012, available at: <http://www.niehs.nih.gov/news/newsletter/2012/7/spotlight-oldenepa>.

¹⁸ Bipartisan Policy Center’s Science for Policy Project, “Improving the Use of Science in Regulatory Policy,” August 5, 2009, available at: <http://bipartisanpolicy.org/sites/default/files/BPC%20Science%20Report%20final.pdf>.

¹⁹ NRC 2014 IRIS Report Press Release, *supra*, note 14.

- EPA should develop templates for narrative justifications of the evidence integration process and its conclusions, and work to ensure that its guidelines for integration are uniform for cancer and noncancer outcomes;
- In addition to hazard identification, IRIS assessments derive toxicity values for given substances when data allow. NRC was encouraged by the improvements that EPA has made in this area, particularly the shift away from choosing one study as the “best” study for deriving a toxicity value and toward deriving and graphically presenting multiple candidate values. EPA, however, should develop formal methods for combining results of multiple studies and selecting the final IRIS values with an emphasis on achieving a transparent and replicable process;
- To ensure that the IRIS program provides the best assessments possible, the committee recommended that EPA develop a plan for strategically updating its methodology, systematically addressing any identified inefficiencies, and continually evaluating whether the IRIS teams have the appropriate expertise and training.

Chairman BROWN. Good afternoon. This joint hearing of the Subcommittee of Oversight and the Subcommittee on Environment will come to order. Good afternoon, everyone. We welcome you to today's joint hearing. In front of you are packets containing the written testimony, biographies, and truth in testimony disclosures for today's witnesses.

Before we get started, since this is a joint hearing involving two Subcommittees, I want to explain how we will operate procedurally, so all Members understand how the question and answer period will be handled. We will recognize those Members present at the gavel in order of seniority on the Full Committee, and those coming in after the gavel will be recognized in the order of arrival.

And before I give my opening statement, I want to thank—publicly thank the witnesses, as well as Members, and staff on both sides for your flexibility. We have a long series of votes that are going to occur about 2:30, 2:45 this afternoon. We wanted to have plenty of time for Members, as well as the witnesses, to give their statements and ask and answer questions, and so I deeply appreciate everyone's flexibility in this. Now the Chairman recognizes himself for five minutes for an opening statement.

Again, I would like to welcome and thank all of our witnesses for being here today, and for your flexibility in coming in early to accommodate our vote schedule. We don't have control over such matters, so I especially appreciate you all and the Members' cooperation.

Over the past decade, this Committee has held many oversight hearings to examine the EPA's Integrated Risk Information System, or IRIS program. As you all know, IRIS was established three decades ago to provide a single source of information on the risk associated with exposure to environmental chemicals for use by EPA regulatory offices, states, the international community, as well as industry.

Unfortunately, the program has come under increased scrutiny as a result of issues related to the pace of assessments, the lack of transparency, and failure to develop and use consistent approaches to weighing evidence, and characterizing risk in a manner divorced from actual human exposures.

This scrutiny has come in many forms. Internally, from the EPA program offices, which have established their own chemical assessments separate from ours, as well as other federal agencies, including the White House, and externally from stakeholder groups that have increasingly weighed in to express their concern about IRIS assessments. Even the U.S. Government Accountability Office placed the program on its high risk series, a list it provides to Congress every two years, for being at high risk for waste, fraud, abuse, and mismanagement, or in need of broad based transformation.

Congress, and especially this Committee, has shined a spotlight on the IRIS program for several years, particularly as the National Research Council has been directed to review some of the more complex and challenging IRIS assessments. One such example is the 2011 formaldehyde assessment. When the NRC published their review, it went beyond its charge to add a very pointed and critical chapter seven in their report that offered recommendations and

suggestions on how EPA could improve the IRIS process. That eventually led to the NRC report published this May, which identified “substantial improvements” in the initial stages of EPA’s proposed changes to the IRIS program.

That is quite a turnaround from the 2011 report, and I was pleased to read that, just as I was pleased to read when EPA announced two years ago that it had tapped Dr. Ken Olden to lead the agency’s National Center for Environmental Assessment. Dr. Olden has been a refreshing ambassador for the IRIS program, and I applaud his commitment to an open and transparent IRIS process that includes early communication, and increased opportunities for meaningful stakeholder input.

But it is clear that the objective of transparency is not a sentiment shared by all. Unfortunately, we have seen opposition to openness, transparency, and greater public comment from some corners. Sunshine is the only way to ensure that this reform effort succeeds, and anti-industry conspiracy theories, and the boycotting of public meetings do not help the program improve. Dr. Olden and his staff should be commended for opening up the process to all stakeholders, and I greatly appreciate your efforts, Dr. Olden, in that regard.

With that, I am interested in learning more about EPA’s timeline on when it expects to complete its reform process, and, more importantly, when it will publish IRIS assessments that reflect the recommendations and suggestions offered by the NRC to substantially improve the program.

IRIS will be considered a success when the science behind the assessments is viewed by all stakeholders as rigorous and accurate. The real metric for progress for IRIS should be the actual content of the assessments. Are they credible? Do they correctly characterize risk and uncertainty? Can users trust them? Are they overly conservative in a way that limits the options available to risk managers? If EPA develops such guidelines, handbooks, or policies, then fails to consistently follow them, we will have spent years, and millions of taxpayers’ dollars to reform IRIS on paper.

As a physician, I understand how important it is to ensure the best possible scientific methods are being utilized to protect our most sensitive populations, including children, pregnant women, and the elderly, all from undue harm. Because of this widespread use, we must be certain that the IRIS program is using the best possible science, and scientific process, in a timely fashion to publish assessments that engender confidence by all stakeholders. Anything less than that is a mission not accomplished. Thank you.

[The prepared statement of Mr. Broun follows:]

PREPARED STATEMENT OF SUBCOMMITTEE ON OVERSIGHT
CHAIRMAN PAUL BROUN

Good afternoon. I want to welcome and thank all of our witnesses for being here today.

Over the past decade, this Committee has held many oversight hearings to examine the EPA’s Integrated Risk Information System, or IRIS program. As you all know, IRIS was established three decades ago to provide a single source of information on the risks associated with exposure to environmental chemicals for use by EPA regulatory offices, states, the international community, and industry. Unfortunately, the program has come under increased scrutiny as a result of issues related

to the pace of assessments, lack of transparency, failure to develop and use consistent approaches to weighing evidence, and characterizing risks in a manner divorced from actual human exposures.

This scrutiny has come in many forms: internally, from EPA program offices—who have established their own chemical assessments separate from IRIS - as well as other federal agencies, including the White House, and externally, from stakeholder groups who have increasingly weighed in to express their concerns about IRIS assessments. Even the U.S. Government Accountability Office placed the program on its High-Risk series, a list it provides to Congress every two years, for being at high risk for waste, fraud, abuse, and mismanagement or in need of broad-based transformation.

Congress, and especially this Committee, has shined the spotlight on the IRIS program for several years, particularly as the National Research Council has been directed to review some of the more complex and challenging IRIS assessments. One such example is the 2011 formaldehyde assessment. When the NRC published that review, it went beyond its charge to add a very pointed and critical Chapter Seven in the report that offered recommendations and suggestions on how EPA could improve the IRIS process. That eventually led to the NRC report published this May, which identified “substantial improvements” in the initial stages of EPA’s proposed changes to the IRIS program.

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But it is clear that the objective of transparency is not a sentiment shared by all. Unfortunately, we have seen opposition to openness, transparency, and greater public comment from some corners. Sunshine is the only way to ensure that this reform effort succeeds, and anti-industry conspiracy theories and the boycotting of public meetings do not help the program improve. Dr. Olden and his staff should be commended for opening up the process to all stakeholders.

With that, I am interested in learning more about EPA’s timeline on when it expects to complete its reform process, and more importantly, when it will publish IRIS assessments that reflect the recommendations and suggestions offered by the NRC to substantially improve the program. IRIS will be considered a success when the science behind the assessments is viewed by all stakeholders as rigorous and accurate. The real metric for progress for IRIS should be the actual content of the assessments. Are they credible? Do they correctly characterize risk and uncertainty? Can users trust them? Are they overly conservative in a way that limits the options available to risk managers? If EPA develops useful guidelines, handbooks, or policies, then fails to consistently follow them, we will have spent years and millions of dollars to reform IRIS on paper.

As a physician, I understand how important it is to ensure the best possible scientific methods are being utilized to protect our most sensitive populations, including, children, pregnant women, and the elderly, from undue harm. Because of its widespread use, we must be certain that the IRIS program is using the best possible science and scientific process in a timely fashion to publish assessments that engender confidence by all stakeholders. Anything less than that is a mission not accomplished.

Thank you. I now recognize the Ranking Member, the gentleman from New York, Mr. Maffei, for an opening statement.

Chairman BROWN. And now I recognize the Ranking Member of the Environment Subcommittee, Ms. Bonamici, for an opening statement.

Ms. BONAMICI. Thank you very much, Mr. Chairman. And thank you to our witnesses for testifying before the Subcommittees today. I want to note that the absence of more Members on this side is not indicative of our concern about the issue. The change in time and conflicting hearings are to blame.

So I also want to start by emphasizing, on behalf of my colleagues on my side of the aisle, that we are not anti-industry, nor are we opposed to the development of new chemicals. We simply want to ensure that scientific information is available to determine

the health effects that might result from exposure. This is about protecting human health. I am glad you recognize that, Mr. Chairman.

The Integrated Risk Information System, IRIS, was intended to be a database that would provide a comprehensive source of best information on the health risks of chemicals. Approximately 700 new chemicals enter the market every year, joining about 85,000 industrial chemicals already in use. Companies that manufacture, distribute, or use these chemicals are not required to demonstrate that the chemicals are safe.

When a company wants to introduce a new chemical, the company notifies the EPA, but the company is not required to share any data regarding the safety of that chemical. EPA cannot even request safety data unless it can show that there is a potential risk by pointing to available academic or industry data. It often takes many years before harms associated with the chemical can begin to be identified. Thus, there is no good public safety check in place.

There is what seems to be an obvious need for transparency. Despite that, since the 1990s, the industry appears to have used some strategies to try to slow IRIS entries, tie EPA up in lengthy reviews and inter-agency dialogues, or generally cast doubt on claims that a particular chemical might have an adverse health effect.

For example, during the Bush Administration, the Office of Management and Budget hired a toxicologist and epidemiologist to run so-called peer reviews of draft IRIS entries, a policy that resulted in endless requests from OMB that EPA go back and look at different literature, or make minor changes to their findings. The Bush Administration also created an inter-agency review process that allowed agencies with significant pollution problems to challenge the EPA IRIS drafts. Production of new IRIS assessments was so slow that the GAO put IRIS on their watch list—you mentioned that, Mr. Chair—and there was a bipartisan push to let EPA take control of their program and expand their productivity.

The Obama Administration sought to strengthen IRIS, and moved OMB into the background while lessening unnecessary inter-agency review mechanisms. The response from those who are opposed to IRIS has been to call on the National Research Council to continually review IRIS assessments. The NRC was drawn into IRIS several times prior to the 2011 formaldehyde review. In each case, they largely supported EPA's findings, but offered advice about how to complete more systematic reviews, and how to improve the science assessments. Invariably, the overall assessments of EPA's findings were lost in the noise about what the EPA did not do, or could have done better.

The 2011 report was a little different. The National Research Council used that report to praise the substantial improvements—thank you, Dr. Olden—made by the EPA thus far, and offer a road map how to make IRIS more efficient to accelerate and streamline the assessments. EPA embraced the advice of the NRC, and, as the most recent report acknowledges, has made significant progress in putting into place the process reforms recommended in 2011.

Now we are faced with a question. What is the National Academy's off-ramp strategy for getting out of the business of doing endless IRIS reviews? Questions have been raised about whether the

American Chemistry Council may have an interest in keeping IRIS unproductive. Does every NRC report offer an opportunity for criticisms about the quality of the science at the EPA? These are issues we hope you will address today.

At this point I am very interested to hear whether the Academy has reached the end of its productive contributions. If not, where is that point? Frankly, the combination of the 2011 report, the new leadership at the Center for Environmental Assessment, which has focused on building a better relationship with industry, has had the effect of crippling IRIS, rather than putting the EPA on a path to streamline production of IRIS entries. In fact, unless changes are implemented, it very well may cripple the program as much as when OMB was involved, with repeated peer reviews. So I am very interested to hear from Dr. Olden what you intend to do to get production of IRIS assessments moving.

I look forward to the testimony from each of the witnesses. There have been a lot of questions raised, but, importantly, this Committee needs to hear how we are going to get out of the way, let EPA do its job of producing assessments of chemicals that may be suspected of, and may be causing harm to our constituents and our communities. Thank you very much, Mr. Chairman, and I yield back.

[The prepared statement of Ms. Bonamici follows:]

PREPARED STATEMENT OF SUBCOMMITTEE ON ENVIRONMENT
RANKING MINORITY MEMBER SUZANNE BONAMICI

Thank you, Mr. Chairman, and thank you to our witnesses for testifying before our Subcommittees today. I want to start by emphasizing on behalf of my side of the aisle that we are not anti-chemical or opposed to the development of new chemicals—we simply want to assure that scientific information is available to determine the health effects that might result from exposure. This is about protecting human health.

The Integrated Risk Information System, IRIS, was intended to be a database that would provide a comprehensive source of best information on the health risks of chemicals. Approximately seven hundred new chemicals enter the market every year, joining about 85,000 industrial chemicals already in use. Companies that manufacture, distribute, or use these chemicals are not required to demonstrate that the chemicals are safe.

When a company wants to introduce a new chemical, the company notifies the EPA, but the company is not required to share any data regarding the safety of that chemical. EPA cannot even request safety data unless it can show there is a potential risk by pointing to available academic or industry data. It often takes many years before harms associated with a chemical can begin to be identified, thus there is no good public safety check in place.

There is what seems to be an obvious need for transparency. Despite that, since the 1990s the chemical industry appears to have used strategies to try to slow IRIS entries, tie EPA up in lengthy reviews and interagency dialogues, and generally cast doubt on claims that a particular chemical might have an adverse health effect. For example, during the Bush Administration, the Office of Management and Budget hired a toxicologist and an epidemiologist to run so-called “peer reviews” of draft IRIS entries, a policy that resulted in endless requests from OMB that EPA go back and look at different literature or make minor changes to their findings. The Bush Administration also created an interagency review process that allowed agencies with significant pollution problems to challenge the EPA IRIS drafts. Production of new IRIS assessments was so slow that GAO put IRIS on their “watch list,” and there was a bipartisan push to let EPA take control of their program and expand their productivity.

The Obama Administration sought to strengthen IRIS, and moved OMB into the background while lessening unnecessary interagency review mechanisms. The response from those who are opposed to IRIS’s work has been to call on the National

Research Council to continually review IRIS assessments. The NRC was drawn into IRIS several times prior to the 2011 Formaldehyde review. In each case they largely supported EPA's findings, but offered advice about how to complete more systematic reviews and how to improve the science assessments. Invariably, the overall endorsements of EPA's findings were lost in the noise about what EPA did not do or could have done better.

The 2011 report was a little different. The National Research Council (NRC) used that report to praise the substantial improvements made by EPA thus far, and offer a road map for how to make IRIS more efficient, and to accelerate and streamline the assessments. EPA embraced the advice of the NRC and, as the most recent report acknowledges, has made significant progress in putting into place the process reforms recommended in 2011. Now we are faced with a necessary question: what is the National Academy's off-ramp strategy for getting out of the business of doing endless IRIS reviews? Organizations such as the American Chemistry Council may have an interest in keeping IRIS unproductive, and discrediting its work could keep the Academy busy as every NRC report offers an opportunity for criticisms about the quality of the science at EPA. At this point, I am very interested to hear whether the Academy has reached the end of its productive contributions. If they have not reached that point, where might that point be?

Frankly the combination of the 2011 report and the new leadership at the National Center for Environmental Assessment, which has focused on building a better relationship with industry, has had the effect of crippling IRIS rather than putting the EPA on a path to streamlined production of IRIS entries. In fact, unless changes are implemented, it may very well cripple the program as much as when OMB was involved with repeated "peer reviews." So I am very interested to hear from Dr. Olden about what he intends to do to get production of IRIS assessments moving.

I look forward to the testimony from each of the witnesses. But importantly, this Committee needs to hear how we are going to get out of the way and let EPA do its job of producing assessments of chemicals that are suspected of and may be causing harm to our constituents and our communities.

Chairman BROWN. Thank you, Ms. Bonamici. Now the Chair recognizes the Chairman of the Subcommittee on Environment, the gentleman from Arizona, Mr. Schweikert, for his opening statement. You are recognized for five minutes.

Mr. SCHWEIKERT. Thank you, Mr. Chairman. We will do this quickly, to be economical with time, because of the votes coming up. Welcome to the chaos of this time of year.

I have three quick things. One, I need to say goodbye to Mr. Woods here, though his unwillingness to shave demonstrates he knows he is leaving us this coming week. Number two, something that almost has never happened in my couple years around here, I talked to some folks who care very much about what is done here, and they actually said nice things about you, Dr. Olden. You have no idea how rare it is to hear nice things about anyone around here.

And, number three, one of the comments that came up, both from some folks I met who you consider on the left and the right, is the encouragement and the hope that the continued movement to be more transparent with data, so folks can review and understand, continues. There was a great warmth from both sides that was heading in the right direction. With that, Mr. Chairman, I yield back.

[The prepared statement of Mr. Schweikert follows:]

PREPARED STATEMENT OF ENVIRONMENT SUBCOMMITTEE
CHAIRMAN DAVID SCHWEIKERT

EPA's Integrated Risk Information System, or "IRIS," is designed to provide quantitative and non-quantitative toxicity information for a suite of chemicals. The purpose of this program is to provide basic scientific determinations about what is a safe level and to be used by both EPA program offices and States.

This program has never been authorized by Congress and, over the last decade, has been strongly criticized by the National Academy of Sciences, the Government Accountability Office (it was listed as a “High risk” program in 2009 and remains on the list), the environmental community, industry, and both parties.

The National Research Council rightly found that critical reforms that promote greater openness, transparency, and stakeholder engagement are currently underway by EPA, led by Dr. Ken Olden.

It is important to note that these limited reforms are simply a work in progress—not a single complete assessment has benefited from this new framework. The NRC report was a snapshot in time, and even these limited reforms have been criticized in some corners.

Specifically, the NRC called on EPA to:

- Increase the transparency of how IRIS assessments are conducted and of the criteria EPA uses;
- Adopt better methodologies for systematic review of the literature, for evaluating evidence, and for integrating evidence across different types of scientific information;
- Rely on more high quality studies;
- Conduct better peer review;
- Increase the role of outside experts; and
- Better manage the program to improve its efficiency and to stay current with scientific advances.

Most of these reforms have focused on process, but there are key areas in the content of these assessments that limit their credibility. States, industry, and the public do not trust the IRIS assessments.

The former Science Advisor for EPA recently wrote in *Nature* that: “Fundamentally, the EPA should replace risk values that are built on science-policy assumptions with risk estimates that acknowledge underlying uncertainties. The EPA’s definitive values are illusions; they conceal uncertainty that cannot be resolved scientifically.”

Chairman BROUN. Well, that was quick. Thank you, Mr. Schweikert. If there are Members who wish to submit additional opening comments or statements, your statements will be added to the record at this point.

Chairman BROUN. At this time I would like to introduce our panel of witnesses. Our first witness is Dr. David Dorman, member of the National Research Council’s Committee to Review the EPA’s IRIS Process.

Our second witness, and star, is Dr. Ken Olden, Director of the National Center for Environmental Assessment at the U.S. Environmental Protection Agency. And, I just want to reiterate what Mr. Schweikert said. It is just so nice to have good comments, and it is rare around here, Dr. Olden.

Our third witness is Ms. Rena Steinzor, Professor of Law at the University of Maryland, and President of the Center for Progressive Reform. Glad to have you, as well as our final witness, Mr. Michael Walls, Vice President of Regulatory and Technical Affairs at the American Chemistry Council.

Now, as the witnesses should know, spoken testimony is limited to five minutes each, and if you would please try to limit your comments to five minutes. I am not going to gavel you down, but we do have votes forthcoming fairly quickly. So if you would, please try to limit your comments to five minutes, after which Members of the committee will have five minutes each to ask questions.

It is the practice of the Subcommittee on Oversight to receive testimony under oath. If you would all please stand. Raise your right hand. Do you solemnly swear to affirm to tell the whole truth, and nothing but the truth, so help you God? Dr. Dorman? Okay,

very good. You may be seated. Let the record reflect that the witnesses participating have all taken the oath.

I now recognize Dr. Dorman for five minutes.

**TESTIMONY OF DR. DAVID DORMAN,
MEMBER, COMMITTEE TO REVIEW EPA'S IRIS PROCESS,
NATIONAL RESEARCH COUNCIL**

Dr. DORMAN. Okay. Good afternoon, Dr. Broun, Chairman Schweikert, Ranking Member Bonamici, and other Members of the Subcommittees. My name is David Dorman. I am a professor of toxicology at North Carolina State University, and I served as a member of the National Research Council Committees to review the IRIS process, and the NRC Committee to review EPA's draft IRIS assessment of Formaldehyde. I am pleased to appear before you today to discuss aspects of the report, "Review of EPA's Integrated Risk Information System Process", which was released earlier this year, in May of 2014.

This report, which I have a copy of, and—was written by a 15 member committee of the National Research Council of the National Academies. The committee was asked to assess the scientific, technical, and process changes being implemented or planned by EPA, and to recommend modifications, or additional changes, as appropriate, to try to improve the scientific and technical performance of the IRIS process. Recommendations in the earlier NRC formaldehyde report, as mentioned earlier, provided the impetus for the changes to EPA's IRIS program.

Overall, the IRIS committee found that the changes that EPA has proposed and implemented to various degrees constitute substantial improvements in the IRIS process. If current trajectories are maintained, some of the inconsistencies identified in our report are addressed, and planned revisions still to be implemented are successfully completed, the IRIS process will become much more effective and efficient in achieving the program's basic goal of developing assessments that provide an evidence-based foundation for ensuring that chemical hazards are optimally addressed, and assessed through a transparent and replicable approach.

The IRIS committee reviewed and evaluated the overall process, and each individual step of the process, and the changes that EPA has made, or is planning to make, and offered recommendations. Additionally, the IRIS committee identified three broad areas on which the EPA should focus attention.

First, EPA's assessment methods will need to be updated in a continuing strategic process, and EPA should develop a plan for doing so. Second, the sources of inefficiencies in the IRIS process need to be identified and addressed systematically. Third, EPA management needs to evaluate human and technologic resources that are needed to conduct IRIS assessments, and support methodologic research, and the implementation of new approaches. The IRIS committee emphasized that if sufficient financial and staff resources are not available to EPA, then it will not be able to continue to improve the IRIS program, and keep pace with scientific advancement.

As noted, the IRIS committee found that substantial improvements in the IRIS process have been made, and it is clear that

EPA has embraced, and is acting on the recommendations in the NRC formaldehyde report. The NRC formaldehyde committee recognized that these suggested changes would take several years, and an extensive effort on the part of EPA staff to implement. Substantial progress, however, has been made in a short time, and the IRIS committee's recommendation should be seen as building on the progress that EPA has already made.

Thank you for the opportunity to testify, and I would be happy to answer any questions that the Committee would like me to address. Thank you.

[The prepared statement of Dr. Dorman follows:]

REVIEW OF EPA'S INTEGRATED RISK INFORMATION SYSTEM (IRIS) PROCESS

Statement of

David C. Dorman, DVM, PhD, DABT, DABVT

Professor of Toxicology
North Carolina State University

and

Member, Committee to Review the IRIS Process
Board on Environmental Studies and Toxicology
Division on Earth and Life Studies
National Research Council
The National Academies

before the
Subcommittees on Oversight and Environment
Committee on Science, Space, and Technology
U.S. House of Representatives

July 16, 2014

Good morning, Chairmen Broun and Schweikert and members of the subcommittees. My name is David Dorman. I am a professor of toxicology at North Carolina State University. I served as a member of the National Research Council (NRC) Committee to Review the IRIS Process and the NRC Committee to Review EPA's Draft IRIS Assessment of Formaldehyde. The NRC is the operating arm of the National Academy of Sciences, National Academy of Engineering, and the Institute of Medicine of the National Academies, chartered by Congress in 1863 to advise the government on matters of science and technology.

I am pleased to appear before you today to discuss aspects of the report, *Review of EPA's Integrated Risk Information System (IRIS) Process*, which was released on May 6, 2014. Our review of the IRIS process was written by a 15-member committee with a wide array of scientific expertise, appropriate to the task. The committee was asked to assess the scientific, technical, and process changes being implemented or planned by EPA and recommend modifications or additional changes as appropriate to improve the scientific and technical performance of the IRIS program. It was also asked to review current methods for evidence-based reviews and recommend approaches for weighing scientific evidence for chemical hazard and dose-response assessments. We have provided a copy of the report for the subcommittees, and the summary is attached.

The IRIS program is responsible for developing toxicologic assessments of environmental contaminants. Over the last decade, the NRC has reviewed some of the more complex and challenging IRIS assessments, including those of formaldehyde, dioxin, and tetrachloroethylene. In 2011, an NRC committee released its review of the IRIS formaldehyde assessment. Like other NRC committees that had reviewed IRIS assessments, the formaldehyde committee identified deficiencies in the specific assessment and more broadly in some of EPA's general approaches and specific methods. Although that committee focused on evaluating the IRIS formaldehyde assessment, it provided general suggestions for improving the IRIS process and a roadmap for its revision (in Chapter 7 of that report) in case EPA

decided to move forward with changes to the process. After release of the NRC formaldehyde report, Congress instructed EPA to incorporate as appropriate the NRC recommendations. The report of the IRIS committee reviews the resulting changes that have been made to the IRIS assessment process.

Overall, the IRIS committee found that the changes that EPA has proposed and implemented to various degrees constitute substantial improvements in the IRIS process. If current trajectories are maintained, inconsistencies identified in the committee's report are addressed, and planned revisions still to be implemented are successfully completed, the IRIS process will become much more effective and efficient in achieving the program's basic goal of developing assessments that provide an evidence-based foundation for ensuring that chemical hazards are optimally assessed through a transparent and replicable approach.

Specifically, the IRIS committee found that EPA has implemented a new document structure that streamlines the assessments, drafted a preamble and a handbook that provide descriptions of the IRIS process, formed chemical assessment support teams to oversee the assessment-development process and ensure consistency among assessments, and implemented several initiatives to increase stakeholder input into the IRIS process. Those changes should substantially strengthen the IRIS process. The committee noted, however, that EPA still needs to indicate how the general principles described in the preamble are applied in a given assessment, it might also require outside experts to fill gaps in expertise in specific areas, and it might consider ways to provide technical assistance to under-resourced stakeholders to help them develop and provide input into the IRIS process.

The IRIS committee reviewed each step of the IRIS process and the changes that EPA has made or is planning to make, evaluated progress, and offered recommendations. For evidence identification, EPA has substantially improved its approach and is well on its way to adopting a more rigorous approach that when fully implemented should meet the recent Institute of Medicine standards for systematic review.

For evidence evaluation, EPA correctly identifies important study attributes but does not describe how it will assess risk of bias in the identified studies. Risk of bias is related to internal validity of a study and reflects study-design characteristics that can introduce a systematic error that might affect the magnitude and even the direction of the apparent effect. The IRIS committee recommended that EPA conduct risk-of-bias assessments on studies that are used as primary data sources, and that the results of the evaluations be fully described and reported in IRIS assessments. For evidence integration, EPA is moving toward a more structured approach. The IRIS committee described several qualitative and quantitative options in its report and suggested that EPA adopt the approach that best fits its plan for the IRIS program.

However, the committee emphasized that quantitative approaches to integrating evidence will be increasingly needed and useful to EPA, and the agency should seriously consider expanding its ability to perform quantitative modeling for evidence integration. Regardless of the approach, EPA should develop templates for informative narrative justifications of the evidence-integration process and the conclusions reached. Finally, for dose-response assessment and calculation of toxicity values, the IRIS committee was encouraged by the improvements, particularly the shift away from choosing one study as the “best” one for deriving a toxicity value and toward deriving and graphically presenting multiple candidate toxicity values. However, the IRIS committee recommended that EPA develop formal methods for combining the results of multiple studies and selecting the final IRIS toxicity values and that EPA develop guidelines for uncertainty analysis and communication in the context of IRIS.

To ensure that the IRIS program provides the best assessments possible, the IRIS committee identified three broad areas on which EPA should focus attention. First, the assessment methods will need to be updated in a continuing, strategic fashion, and EPA should develop a plan for doing so. Second, the sources of inefficiencies in the IRIS process need to be identified and addressed systematically. Third, EPA management needs to evaluate the human and technologic resources that are needed to conduct IRIS assessments and support methodologic research and the implementation of new approaches. The IRIS

committee emphasized that if sufficient financial and staff resources are not available to EPA, it will not be able to continue to improve the IRIS program and keep pace with scientific advancements.

As noted, the IRIS committee found that substantial improvements in the IRIS process have been made, and it is clear that EPA has embraced and is acting on the recommendations in the NRC formaldehyde report. The NRC formaldehyde committee recognized that its suggested changes would take several years and an extensive effort by EPA staff to implement. Substantial progress, however, has been made in a short time, and the IRIS committee's recommendations should be seen as building on the progress that EPA has already made. The IRIS committee recommended further peer review as the EPA completes the revisions.

Thank you for the opportunity to testify. I would be happy to answer any questions the subcommittees might have.

Summary

The Integrated Risk Information System (IRIS) is a program within the US Environmental Protection Agency (EPA) that is responsible for developing toxicologic assessments of environmental contaminants. IRIS assessments contain hazard identifications and dose-response assessments of various chemicals that cover cancer and noncancer outcomes. Although the program was created to increase consistency among toxicologic assessments within the agency, other federal agencies, various state and international agencies, and other organizations have come to rely on IRIS assessments for setting regulatory standards, establishing exposure guidelines, and estimating risks to exposed populations. Over the last decade, the National Research Council (NRC) has been asked to review some of the more complex and challenging IRIS assessments, including those of formaldehyde, dioxin, and tetrachloroethylene. In 2011, an NRC committee released its review of the IRIS formaldehyde assessment. Like other NRC committees that had reviewed IRIS assessments, the formaldehyde committee identified deficiencies in the specific assessment and more broadly in some of EPA's general approaches and specific methods. Although the committee focused on evaluating the IRIS formaldehyde assessment, it provided general suggestions for improving the IRIS process and a roadmap for its revision in case EPA decided to move forward with changes to the process.

After release of the formaldehyde report, Congress held several hearings to examine the IRIS program. The House Report (112-151) that accompanied the Consolidated Appropriations Act of 2012 (Public Law 112-74) stated that "EPA shall incorporate, as appropriate, based on chemical-specific datasets and biological effects, the recommendations...of the National Research Council's Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde into the IRIS process." To ensure that EPA adequately considers the recommendations, Congress requested that NRC assess the scientific, technical, and process changes being implemented or planned by EPA and recommend modifications or additional changes as appropriate to improve the scientific and technical performance of the IRIS program. This committee, the Committee to Review the IRIS Process, was convened by NRC as a result of that request. In addition to reviewing the changes in the IRIS program, the committee was asked to review current methods for evidence-based reviews and recommend approaches for weighing scientific evidence for chemical hazard and dose-response assessments. The present report provides the committee's review and recommendations, which are organized around the general depiction of the IRIS assessment process shown in Figure S-1.

SYSTEMATIC REVIEW

In 2011, the same year that the NRC formaldehyde report was released, the Institute of Medicine (IOM) released a report that recommended standards for systematic review.¹ As defined by IOM, systematic review "is a scientific investigation that focuses on a specific question

¹IOM (Institute of Medicine). 2011. Finding What Works in Health Care: Standards for Systematic Reviews. Washington, DC: The National Academies Press.

Overall, the changes that EPA has proposed and implemented to various degrees constitute substantial improvements in the IRIS process. If current trajectories are maintained, inconsistencies identified in the present report are addressed, and objectives still to be implemented are successfully completed, the IRIS process will become much more effective and efficient in achieving the program's basic goal of developing assessments that provide an evidence-based foundation for ensuring that chemical hazards are assessed and managed optimally.

Specifically, the present committee finds that the new document structure improves the organization of and streamlines the assessments and reduces redundancies. EPA's use of evidence tables and graphic displays has also reduced text volume and enhanced clarity and transparency. The new approaches bring IRIS assessments much more into line with the state of practice for systematic reviews. The preamble is a useful statement, which will presumably be updated as methods and procedures are modified and updated, but it does not substitute for an overview that indicates how the general principles in the preamble have been applied in any given assessment. The handbook is critical for providing consistency among the assessment teams and contributors, and the final version should be peer-reviewed to ensure that the document is on target and provides the needed guidance.

The committee is encouraged by the efforts to strengthen the overall scientific expertise in the assessment process through the addition of the CASTs and recommends that IRIS assessments clearly identify the members of all teams involved in the development of any given assessment. To strengthen the process further, experts from outside EPA and the government might be needed to fill gaps in expertise in specific areas. Experts should be engaged when needed to augment teams and to conduct peer review of the draft and final assessments.

Finally, the committee applauds EPA initiatives to involve stakeholders in the IRIS process earlier and more fully. Those initiatives are likely to improve assessment quality and to strengthen the program's credibility. However, not all stakeholders who have an interest in the IRIS process have the same scientific or financial resources to provide timely comments, and expanded opportunities for stakeholder involvement might lead to a further imbalance of public input. Therefore, similar to other EPA technical-assistance programs, EPA should consider ways to provide technical assistance to under-resourced stakeholders to help them to develop and provide input into the IRIS process.

PROBLEM FORMULATION AND PROTOCOL DEVELOPMENT

As noted, EPA is incorporating principles of systematic review as it revises the IRIS process. Critical elements of conducting a systematic review include formulating the specific question that will be addressed (problem formulation) and developing the protocol that specifies the methods that will be used to address the question (protocol development). Although the NRC formaldehyde report did not provide any specific recommendations regarding those elements, the present committee found that some discussion of them is warranted.

A major challenge for EPA in the problem-formulation step is to determine what adverse outcomes should be evaluated in a specific IRIS assessment. The committee suggests a three-step process for conducting problem formulation. First, with the support of an information specialist who is trained in conducting systematic reviews, EPA should perform a broad literature search designed to identify possible health outcomes associated with the chemical under investigation. The broad search should not be confused with the comprehensive literature search that is conducted for evidence identification in a systematic review (see Figure S-1); some EPA materials do not sufficiently distinguish between the two. Second, a table should be constructed to guide the formulation of specific questions that would be the subjects of specific systematic reviews. The table could be organized by the lines of evidence typically available to EPA (human, animal, and mechanistic studies) and the various health outcomes to investigate. Third, the table should be examined to determine which outcomes warrant a systematic review and how to define the systematic-review question, such as, Does exposure to chemical X result in neurotoxic effects?

describe how it will assess risk of bias in the identified studies. The committee notes that assessing the quality of the study is not equivalent to assessing the risk of bias in the study. An assessment of study quality evaluates the extent to which the researchers conducted their research to the highest possible standards and how a study is reported. Risk of bias is related to the internal validity of a study and reflects study-design characteristics that can introduce a systematic error (or deviation from the true effect) that might affect the magnitude and even the direction of the apparent effect. An assessment of risk of bias is a key element in systematic-review standards; potential biases must be assessed to determine how confidently conclusions can be drawn from the data.

The committee emphasizes the importance of assessing risk of bias for all study types. Although several approaches are described in the present report, the committee is not recommending the adoption of any specific approach. For a scientifically defensible method, however, EPA should select assessment tools for which empirical evidence links an assessment item with an associated risk of bias. Standardized methods might need to be developed, and EPA might need to conduct or support research on the development and evaluation of empirically based instruments for assessing bias in human, animal, and mechanistic studies relevant to chemical-hazard identification. It might want to consider pooling data across IRIS assessments to determine whether, among various contexts, candidate risk-of-bias items are associated with overestimates or underestimates of effect.

Incorporating risk-of-bias assessments into the IRIS assessment process might take some time, and approaches will depend on the complexity and extent of data on a chemical and the resources available to EPA. An important limitation of all existing tools for assessing study methods is that research reports might not include sufficient details to enable assessment. Consequently, EPA might be hampered by differences in reporting standards for some scientific literature, although the committee expects reporting of toxicology research to improve as risk-of-bias assessments are incorporated into the IRIS process. However, a coordinated effort by government agencies, researchers, publishers, and professional societies will be required to improve the completeness and accuracy of reporting toxicology studies in the near future. Regardless, a risk-of-bias assessment should be conducted on studies that are used by EPA as primary data sources for the hazard identification and dose-response assessment. Whatever approach is adopted, the assessment approach and the results should be fully described and reported in the IRIS assessment.

EVIDENCE INTEGRATION FOR HAZARD IDENTIFICATION

The NRC formaldehyde committee provided several recommendations regarding evidence integration, including reviewing the use of weight-of-evidence guidelines, standardizing an approach to using them, developing uniform language to describe the strength of evidence on non-cancer effects, and providing more integrative and transparent discussions of weight of evidence. As in other recommendations, there is an emphasis on transparency and standardization of approach. In response, EPA has provided guidelines in the preamble for what considerations ought to inform the experts who are charged with integrating human, animal, and mechanistic evidence, and it gives extensive guidance on the qualitative categorization that the experts should use, but it articulates no systematic process by which the experts are to come to a conclusion. In the handbook, EPA provides extensive guidelines for synthesizing evidence within each category but no guidelines for integrating evidence among categories. The guidelines and the classification schemes offered for epidemiologic and other studies are reasonable, and similar ones have been used by other organizations with similar aims.

The committee appreciates that EPA's improvements for evidence integration are still being developed but offers some options for moving forward. Several qualitative and quantitative options are available for overall evidence integration. Qualitative options include guided expert judgment, such as the approach used by the International Agency for Research on Cancer

dose-response modeling, developing candidate toxicity values, and characterizing confidence and uncertainty in toxicity values has yet to be developed for the draft handbook.

The committee is encouraged by the improvements that EPA has made in the IRIS process for deriving toxicity values, particularly the shift away from choosing one study as the “best” study for deriving a toxicity value and toward deriving and graphically presenting multiple candidate toxicity values. As the program evolves, EPA will need to make the best use of the totality of evidence with increased attention to distinguishing the quality and relevance of studies for assessing human dose-response relationships. That will require EPA to develop clear criteria for judging the relative merits of individual mechanistic, animal, and epidemiologic studies for estimating human dose-response relationships. Although subjective judgment remains an inherent feature of deriving toxicity values, EPA should develop formal methods for combining the results of multiple studies and selecting the final IRIS values with an emphasis on achieving a transparent and replicable process. EPA could also improve documentation of dose-response information by clearly presenting two dose-response values: a central estimate (such as a maximum likelihood estimate or a posterior mean) and a lower-bound estimate for a point of departure from which a final toxicity value is derived.² Reporting both values provides information on statistical uncertainty, such as sampling variation, and makes available to the risk assessor the full range of information. Finally, EPA should develop guidelines for uncertainty analysis and communication in the context of IRIS to support the consistent and transparent treatment of uncertainties.

FUTURE DIRECTIONS

The committee commends EPA for the improvements that it has made in the IRIS assessment-development process and expects the revisions when completed to result in a transformation of the IRIS program. To ensure that the IRIS program provides the best assessments possible, the committee identified three broad areas on which EPA should focus attention. First, the assessment methodology will need to be updated in a continuing, strategic fashion, and EPA should develop a plan for doing so. Specifically, the agency will need to consider how methods relevant to all elements of the process will evolve and how such progress can be tracked and incorporated into the IRIS assessment-development approach. Second, EPA staff, the CASTs, and the Chemical Assessment Advisory Committee should be encouraged to identify inefficiencies in the IRIS process, which should then be addressed systematically by the IRIS program leadership. EPA should continue to pursue development of firm stopping rules for key points throughout the process to guard against delay and should consider working with other agencies to avoid duplication of effort. Third, EPA management needs to evaluate the human and technologic resources that are needed to conduct IRIS assessments and support methodologic research and the implementation of new approaches. If sufficient financial and staff resources are not available to EPA, it will not be able to continue to improve the IRIS program and keep pace with scientific advancements.

Overall, the committee finds that substantial improvements in the IRIS process have been made, and it is clear that EPA has embraced and is acting on the recommendations in the NRC formaldehyde report. The NRC formaldehyde committee recognized that its suggested changes would take several years and an extensive effort by EPA staff to implement. Substantial progress, however, has been made in a short time, and the present committee’s recommendations should be seen as building on the progress that EPA has already made.

²The lower bound becomes an upper bound for a cancer slope factor but remains a lower bound for a reference value.

Brief Bio of David C. Dorman

David C. Dorman is a professor of toxicology in the Department of Molecular Biosciences of North Carolina State University. The primary objective of his research is to provide a refined understanding of chemically induced neurotoxicity in laboratory animals that will lead to improved assessment of potential neurotoxicity in humans. Dr. Dorman's research interests include neurotoxicology, nasal toxicology, pharmacokinetics, and cognition and olfactory in military working dogs. He served as a member of the National Research Council Committee on Animal Models for Testing Interventions Against Aerosolized Bioterrorism Agents, as member and chair of two Committees on Emergency and Continuous Exposure Guidance Levels for Selected Submarine Contaminants and the Committee to evaluate Potential Health Risks from Recurrent Lead Exposure to DOD Firing Range Personnel, and as a member of the Committee to Review EPA's Draft IRIS Assessment of Formaldehyde. He received his DVM from Colorado State University. He completed a combined PhD and residency program in toxicology at the University of Illinois at Urbana-Champaign and is a diplomate of the American Board of Veterinary Toxicology and the American Board of Toxicology.

Chairman BROUN. Thank you, Dr. Dorman. The Chair now recognizes Dr. Olden for five minutes.

**TESTIMONY OF DR. KENNETH OLDEN, DIRECTOR,
NATIONAL CENTER FOR ENVIRONMENTAL ASSESSMENT,
U.S. ENVIRONMENTAL PROTECTION AGENCY**

Dr. OLDEN. Good afternoon, Chairman Broun, Ranking Member Maffei, Chairman Schweikert, and Ranking Member Bonamici, and distinguished Members of the Committee. My name is Kenneth Olden, and I am the director of the National Center for Environmental Assessment, in the Office of Research and Development in the U.S. Environmental Protection Agency. We appreciate your interest in the Integrated Risk Information System, commonly called IRIS. Today I am pleased to report that the changes that we have made in the program over the past two years have been welcomed, and well received.

A May 2014 report by the National Academies National Research Council commended our progress, and recognized that we have made a tremendous amount of progress in a short time. Yes, we are pleased that the NRC committee recognized the progress that we have made. However, it is not time to celebrate, or to declare victory. In fact, we are humbled by the work that remains to be done.

Our vision is to complete the transformation of IRIS into a highly effective world class scientific enterprise. To achieve this objective, the IRIS program has embraced the use of the best science and informational technologies available to estimate the risk from chemical exposures. Furthermore, we have instituted several structural and programmatic changes to ensure transparency, objectivity, and scientific rigor in the assessment process.

In the interest of time, I will highlight three in my oral testimony today. First, we incorporated principles of systematic structured review methodologies to identify, to evaluate, and to integrate data from the three different evidence streams that we use in toxicity—in estimation of toxicity values. These approaches make use of explicit pre-specified rules to select, to evaluate, and to synthesize data relevant to the specific chemical assessment. Such approaches give results that are highly reproducible, and eliminate bias associated with expert judgment.

However, I might add that methodologies used in systematic review and evidence integration were developed for the use of evidence medicine. In such cases, one is comparing effectiveness of Drug A versus Drug B in a chemical trial. In the case of IRIS assessments, we are integrating evidence from three streams, epidemiology, animal studies, and mode of action, or mechanistic studies.

Except for the Bradford-Hill guidelines used in cancer hazard assessment, the effectiveness and potential for risk of bias for integration of evidence from such diverse sources using these methodologies have not been evaluated. While useful in evidence-based medicine, these methodologies may need to be customized for IRIS purposes. However, I caution that we do not want to make the structured process so rigid as to exclude expert judgment. In the

end, we may end up with a process that combines expert judgment with some sort of structured approach.

Second, we instituted activities to proactively engage the public during critical stages of the assessment process. For example, we hold bimonthly IRIS public meetings to discuss scientific issues related to preliminary assessment materials and draft IRIS assessments. These meetings provide opportunity for public input on the literature identified, and evidence tables that we have prepared for use in the assessment. For example, have we failed to identify all the studies pertinent to the assessment? Have we identified the right disease endpoints likely to be caused by the specific chemical exposure?

And finally, to improve quality and consistency of peer review, we have created a standing chemical assessment advisory committee under the auspices of EPA's Scientific Advisory Board to conduct peer review of IRIS assessments. Since we will have regular and frequent interactions with this committee, systemic and recurring problems can be defined and eliminated, and consensus opinions of the committee will provide quality assurance, and will lend credibility to the assessments. Moreover, impetus to be responsive to the peer review recommendations will be much higher. However, it is my job to ensure the quality and integrity of IRIS assessments.

And, in summary, the transformation of IRIS is well underway. As the individual with primary responsibility for the IRIS program, I can assure you that the EPA fully intends to successfully complete the transformation. The recommendations made by the NRC committees are absolutely consistent with our commitment to transparency and scientific excellence. While we are fully cognizant of the urgency to completely implement the NRC recommendations, our number one priority is to get the science and the process right.

Thank you, and I would be pleased to respond to any questions that you might have.

[The prepared statement of Dr. Olden follows:]

Kenneth Olden, Ph.D.
Director, National Center for Environmental Assessment (NCEA)
Office of Research and Development (ORD)
U.S. Environmental Protection Agency (EPA)

*Hearing on Status of Reforms to EPA's Integrated Risk Information System (IRIS) Process
before the
U.S. House of Representatives
Committee on Science, Space, and Technology
Subcommittees on Oversight and the Environment
July 16, 2014*

Good morning, Chairman Broun, Ranking member Maffei, Chairman Schweikert, Ranking member Bonamici and other distinguished members of the two Subcommittees. My name is Kenneth Olden, and I am the director of the National Center for Environmental Assessment in the Office of Research and Development at the U.S. Environmental Protection Agency (EPA). I appreciate the opportunity to talk with you today about EPA's Integrated Risk Information System Program – commonly called IRIS. Specifically, I am pleased to report on the progress we have made in IRIS over the past two years and the actions that are part of our ongoing efforts to enhance this critical program. A number of areas have been enhanced that further strengthen the scientific integrity of assessments, further increase transparency, and further improve productivity.

These changes were reviewed recently by a panel of the National Academies' National Research Council (NRC), who commended our progress and successes and recognized that we have made a tremendous amount of progress in a short period of time. Recommendations from the National Academies help make EPA's science stronger and we value their guidance in gauging our progress. We appreciate the rigorous scientific review of the IRIS program's assessment development process which,

in the end, will help the Agency better protect human health and the environment.

Background and Description of the IRIS Program

EPA's IRIS program plays a critical role in disseminating timely, high-quality and accessible human health risk information on environmental contaminants that may endanger the health of the American public. The IRIS Program provides health effects information on chemicals to which the public may be exposed from releases to air, water, and land and through the use and disposal of products.

IRIS assessments provide a solid scientific foundation for EPA decisions to protect public health under an array of environmental laws. It is important to state that IRIS assessments are not regulations and they are not environmental decisions. Rather, the assessments are a resource that EPA draws on for its decision making process and can also be a resource for other risk assessors and environmental and health professionals in state and local governments and other countries. Given the potential impact that regulatory decisions have on human health and the economy, it is critically important that the IRIS assessment development process be efficient, transparent and, above all, scientifically rigorous.

2011 National Research Council Recommendations for IRIS and Summary of Progress

In April 2011, the National Academies' National Research Council (NRC) provided EPA with recommendations for improving the development of IRIS assessments.¹ The NRC was clear that their intent was not to delay assessments and that fully addressing their recommendations should be a multi-year, continuous improvement process. Consistent with this advice, EPA has been implementing the recommendations using a phased approach.

¹ National Research Council, 2011. Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde.

EPA has since released several draft assessments that represent major advancements in implementing the NRC's 2011 recommendations. EPA immediately adopted NRC's short-term recommendations including increasing transparency and clarity, using more tables and figures to present information and data in IRIS assessments, and editing and streamlining documents to enhance communication. Next EPA implemented the more substantive NRC recommendations which were focused on improving approaches for identifying and selecting the most pertinent studies to inform the assessments; evaluating and describing the strengths and weaknesses of the critical studies in a uniform, clear manner; strengthening the integration of quantitative evidence for hazard identification; establishing clearer criteria for study selection for dose-response analysis, including toxicity values for multiple effects associated with the chemical; routinely considering the use of multiple data sets of combined multiple responses in deriving toxicity values; and increasing overall transparency in dose-response analysis. To address these, EPA's IRIS assessments now include:

- An Executive Summary at the beginning of the assessment that concisely summarizes the major conclusions of the assessment related to hazard characterization and dose response analyses.
- A Preamble that describes how we applied methods, criteria, and existing EPA guidance to develop the assessments. These methods and evaluation criteria are being applied consistently across IRIS assessments.
- A detailed description of the literature search strategy and study evaluation process used to develop the assessment.
- Two distinct sections, Hazard Identification and Dose-Response Analysis, to reduce the volume of text and redundancies and to increase transparency into the process that led to the assessment's conclusions.

- An appendix documenting the implementation of the NRC recommendations to the assessment process as it relates to the individual chemical assessment.
- An appendix summarizing the peer review of the assessment, public comments, and EPA's responses.
- Improved public access to the science basis for the IRIS assessments via the Health and Environmental Research Online (HERO) system.

We have also further strengthened quality control in the IRIS Program through organizational changes that capitalize on EPA's effort to modernize its human and informational resources. Previously, we used individual assessment teams to develop IRIS assessments. We now have discipline-specific workgroups that coordinate across assessments to ensure consistency, deep expertise, advanced scientific understanding, and the ability to solve cross cutting issues common among groups of assessments. The discipline-specific workgroups cover topics related to: reproductive/developmental toxicity, neurotoxicity, respiratory/inhalation toxicity, systemic and general toxicity, immunotoxicity, cancer, epidemiology, toxicity pathways/genetic toxicity, statistics and dose-response analysis, and physiologically-based pharmacokinetic modeling.

The expertise needed for each chemical undergoing assessment by the IRIS Program varies by chemical. The areas of expertise needed are identified in the early stages of planning and document development and the appropriate scientific personnel and discipline-specific workgroups are assigned to lead or assist in the development of the assessment.

We have also formed a group of senior science managers, who report to me, to oversee the work of the chemical assessment teams during the assessment development process. This group ensures

consistency across chemical groups and helps to identify and resolve any implementation challenges or inefficiencies early in the process to ensure the assessments are of the very highest scientific quality.

Finally, we have expanded IRIS quality control measures by developing a draft handbook of procedures for IRIS assessment development. This handbook details the internal processes and evaluation steps to develop assessments and the information management tools to identify and address scientific or data issues that may occur during assessment development.

2013 Enhancements to the IRIS Program

We have also taken more recent steps to further improve IRIS. In July 2013, EPA announced a series of enhancements to the IRIS Program with the goal of improving the scientific integrity of assessments, increasing the productivity of the IRIS Program, and increasing transparency so issues are identified and discussed earlier in the assessment development process.² These enhancements incorporate additional opportunities for stakeholder and public engagement at various stages of the IRIS process, and since announcing them, we have been convening bimonthly IRIS public science meetings to discuss scientific issues related to preliminary assessment materials and draft IRIS assessments. The IRIS enhancements will help ensure transparency throughout the IRIS assessment development process, and they will help ensure that major science decisions are rigorously vetted.

Additionally, the Agency has established a new Chemical Assessment Advisory Committee, under the auspices of the Science Advisory Board, to review draft IRIS assessments. EPA will also consult with the committee on questions regarding the IRIS Program. The committee is comprised of 26

² <http://www.epa.gov/iris/pdfs/irisprocessfactsheet2013.pdf>

highly qualified scientists with a broad range of expertise relevant to human health assessments. This committee will help ensure that IRIS assessment receive rigorous scientific peer review.

Ultimately, these changes will help EPA meet the goal of using the best available science to produce high quality scientific IRIS assessments in a timely and transparent manner. The 2013 IRIS enhancements are in line with the NRC's recommendations related to improving the development of IRIS assessments and advancing risk assessment in general, including the importance of up front planning and scoping in the risk assessment process.³

National Research Council May 2014 Review of the IRIS Process

Two years ago, we asked the NRC to conduct a comprehensive review of the IRIS assessment development process. As part of this review, EPA sent written materials to the NRC which provide information about the changes that have been made or are being made in the IRIS Program along with chemical-specific examples of how the Program is implementing the NRC recommendations.⁴ The NRC considered these materials as they reviewed the IRIS assessment development process.

In May 2014, the NRC released their report reviewing the IRIS assessment development process. In this report, the NRC commends EPA's movement forward in each element of the assessment process and cites substantial improvement in a short period of time. Specifically, the report notes, "overall, the committee finds that substantial improvements in the IRIS process have been made, and it is clear that EPA has embraced and is acting on the recommendations in the NRC formaldehyde report."⁵

³ National Research Council, 2009. Science and Decisions: Advancing Risk Assessment

⁴ <http://www.epa.gov/iris/iris-nrc.htm>

⁵ National Research Council, 2014. Review of EPA's Integrated Risk Information System (IRIS) Process.

Especially appreciated by EPA, the Committee expressed confidence in the current leadership of the IRIS Program and the Agency's commitment to completing the revisions underway. To quote the committee:

"Overall, the changes that EPA has proposed and implemented to various degrees constitute substantial improvements in the IRIS process. If current trajectories are maintained, inconsistencies identified in the present report are addressed, and objectives still to be implemented are successfully completed, the IRIS process will become much more effective and efficient in achieving the program's basic goal of developing assessments that provide an evidence-based foundation for ensuring that chemical hazards are assessed and managed optimally."⁶

The 2014 NRC report provides recommendations that the committee states should be seen as further building on the progress that EPA has already made.

EPA is grateful to the NRC for their thorough and thoughtful review. The NRC reviewed materials that we submitted in the first half of 2013. Since that time, we have continued to evolve, and we have made further changes that are in line with the recommendations in this report. We embrace and will implement the recommendations in the NRC report. We plan to convene a public workshop in October 2014 to address some specific recommendations from this report.

As the director of EPA's National Center for Environmental Assessment – home of the IRIS Program – I can assure you that I fully intend to maintain this critical national Program to the highest standards possible. I have high confidence that the ORD senior management team also provides their unwavering support.

⁶ National Research Council, 2014. Review of EPA's Integrated Risk Information System (IRIS) Process.

In conclusion, EPA is committed to transparency and scientific excellence and we appreciate the scientific community's work – through the National Academy – in helping us meet that commitment. We are committed to a strong, vital, and scientifically sound IRIS Program. We have worked hard to further strengthen the scientific basis underlying the IRIS Program, improve transparency and accessibility, and to streamline processes to be more efficient. As the IRIS Program continues to evolve, we are committed to evaluating how well our approaches promote constructive public discussion with our stakeholders, as well as reviewing how our approaches can more effectively facilitate subsequent assessment development.

I look forward to keeping this Committee updated on our progress, and thank you for the opportunity to appear before you today. I am happy to take any questions you may have at this time.



Dr. Ken Olden joined the National Center for Environmental Assessment in July 2012 with a strong legacy of promoting scientific excellence in environmental health. From 1991-2005, Ken served as the Director of the National Institute of Environmental Health Sciences (NIEHS) and the National Toxicology Program (NTP) in the U.S. Department of Health and Human Services. Ken made history in this role as the first African American to direct one of the National Institutes of Health. In 2005, he returned to his research position as chief of The Metastasis Group in the Laboratory of Molecular Carcinogenesis at the NIEHS, and for academic year 2006-2007, held the position of Yerby Visiting Professor at the Harvard School of Public Health. Most recently, Ken served as the Founding Dean of the School of Public Health at the Hunter College, City University of New York. He has published extensively in peer-reviewed literature, chaired or co-chaired numerous national and international meetings, and has been an invited speaker, often a keynote, at more than 200 symposia. Ken has won a long list of honors and awards including the Presidential Distinguished Executive Rank Award, the Presidential Meritorious Executive Rank Award for sustained extraordinary accomplishments, the Toxicology Forum's Distinguished Fellow Award, the HHS Secretary's Distinguished Service Award, the American College of Toxicology's First Distinguished Service Award, and the National Minority Health Leadership Award. Alone among institute directors, he was awarded three of the most prestigious awards in public health - the Calver Award (2002), the Sedgwick Medal (2004), and the Julius B. Richmond Award (2005). Most recently, he received the Cato T. Laurencin MD, PhD Lifetime Research Award from the National Medical Association Institute, the largest and oldest national organization representing African American physicians and their patients in the United States. He was elected to membership in the Institute of Medicine at the National Academy of Sciences in 1994 and appointed member of the Visiting Committee for the Harvard University Board of Overseers from 2007-2010.

Dr. Olden continued to direct his research group at the NIEHS through 2012.

Dr. Olden holds the following degrees:

- Temple University, Philadelphia, P.H.D., Cell Biology and Biochemistry, 1970.
- University of Michigan, Ann Arbor, M.S., Genetics.
- Knoxville College, B.S., Biology.

Additionally, Ken has numerous honorary degrees from several prestigious colleges and universities.

Recent publications include:

Nishioka et al. (2012). Plasminogen activator inhibitor 1 RNAi suppresses gastric cancer metastasis in vivo. Cancer Science 103:228-232

George et al. (2013). P38 mitogen-activated protein kinase interacts with vinculin at focal adhesions during fatty acid-stimulated cell adhesion. Biochemistry and Cell Biology 91:404-418.

Chairman BROUN. Thank you, Dr. Olden. Ms. Steinzor, you are recognized for five minutes.

**TESTIMONY OF MS. RENA STEINZOR,
PROFESSOR OF LAW, UNIVERSITY OF MARYLAND;
RESIDENT, CENTER FOR PROGRESSIVE REFORM**

Ms. STEINZOR. Thank you for the opportunity to testify this afternoon about how to get EPA's IRIS program back on track. IRIS assessments are invaluable because they are robust and well documented, are summarized clearly and concisely, and are available to anyone who has access to the Internet. Individuals, community groups, public interest organizations, government officials, in short, everyone, not just in this country, but around the world, can get information they need to make well informed decisions about toxic hazards. Conversely, delaying the production of IRIS profiles causes real and devastating harm to public health. It also saves the chemical industry lots of money.

My testimony today makes three points. First, IRIS assessments have once again slowed to a crawl, sinking to the depths of the poor performance achieved under the Bush Administration. The Obama Administration needs to stop jawboning with industry stakeholders, and concentrate on revitalizing this vital initiative.

The highest best use of the National Academy's expertise would be to help the IRIS program identify ways to develop a significantly larger number of robust assessments quickly, on a limited budget. Congress, the EPA administrator, and the National Academies must confront the very serious problem of regulated industry's commandeering the IRIS assessment process by barraging the agency with endless minor repetitive and irrelevant objections to risk assessments.

Unfortunately, although its potential is great, IRIS's promise is compromised by disturbing data gaps. As GAO has reported, IRIS is rapidly becoming one of EPA's walking dead programs. The agency's efforts to fill IRIS's data gaps were largely stymied during the Bush Administration, and not by accident. That administration imposed reforms designed to subject EPA's scientists to a host of political pressures from government agencies with neither scientific expertise, nor an interest in protecting public health and the environment.

The Obama Administration recognized the problem, but its revisions to the IRIS process left key issues unaddressed. Of late, the administration has displayed a disturbing tendency to retreat in the face of a blistering and self-serving industry campaign to stifle this vital program once and for all.

The two National Academies committees responsible for reviewing IRIS have missed golden opportunities to provide constructive advice on how to develop new assessments quickly. Rather than flyspecking the faults of specific IRIS assessments, and subjecting the program as a whole to a round robin of highly critical examination, three issues must be addressed to solve this problem, revamping the IRIS program's agenda, adopting so-called stopping rules, and ending duplicative rounds of stakeholder consultations dominated by regulated industries.

Once EPA starts an IRIS assessment, there must be an end in sight, an assessment must be declared finished, and its results posted on the web. When significant new science is produced suggesting that the numbers must be lowered or raised, EPA can re-examine the profile. But as exemplified by the chromium compound assessment, regulated industries often manage to push EPA onto a treadmill, where it never escapes the wait for another study. The trouble, of course, is that science is always evolving. EPA cannot wait on all the science to resolve itself, and the truth to be announced. That simply is not the nature of the scientific enterprise.

The final problem is the decision by EPA political appointees to deal with the attacks on IRIS by hosting numerous stakeholder engagement events, some tied to specific assessments, others related to broader science issues, or even general concerns about the program as a whole. EPA's political appointees seem to harbor the naïve idea that this process will placate its critics. Instead, endless jawboning has left the agency vulnerable to cynical exploitation.

In sum, let us not lose sight of what is really at stake, the priceless notion that the water we drink and the air we breathe ought to be clean and healthy. Thank you.

[The prepared statement of Ms. Steinzor follows:]

TESTIMONY

Rena Steinzor

Professor, University of Maryland Carey School of Law
and
President, Center for Progressive Reform (www.progressivereform.org)

before the

**Committee on Science, Space, and Technology
Subcommittees on Oversight and Environment**

U.S. House of Representatives

Hearing on

Status of Reforms to EPA's Integrated Risk Information System

July 16, 2014

Chairmen Broun and Schweikert, Ranking Members Maffei and Bonamici, thank you for the opportunity to testify this afternoon about the great importance of the Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) to the protection of public health in the country and around the world.

I am a law professor at the University of Maryland Carey School of Law and the President of the Center for Progressive Reform (CPR) (<http://www.progressivereform.org/>). Founded in 2002, CPR is a network of sixty scholars across the nation dedicated to protecting health, safety, and the environment through analysis and commentary. We have a small professional staff funded by foundations. I joined academia mid-career, after working for the Federal Trade Commission for seven years and the House Energy and Commerce Committee for five years. For seven years, I served as the lawyer for small, publicly-owned electric systems. My work on environmental regulation includes four books, and over thirty articles (as author or co-author). My most recent book, published by the University of Chicago Press, is *The People's Agents and the Battle to Protect the American Public: Special Interests, Government, and Threats to Health, Safety, and the Environment*, co-authored with Professor Sidney Shapiro of Wake Forest University's School of Law, which comprehensively analyzes the state of the regulatory system that protects public health, worker and consumer safety, and natural resources, and concludes that these agencies are under-funded, lack adequate legal authority, and consistently are undermined by political pressure motivated by special interests in the private sector. Cambridge University Press will publish a book I have written entitled *Why Not Jail: Industrial Catastrophes, Corporate Malfeasance, and Government Inaction* this coming January. I have served as consultant to the EPA and testified before Congress many times.

IRIS is a critical element of EPA's efforts to protect people and the environment from the dangers of toxic chemicals. Started as an internal EPA database used to develop toxicological profiles for common chemicals, the program has grown into a much more valuable tool and is renowned throughout the world as a crucial element of governments' efforts to protect their people. IRIS profiles set the reference dose, or RfD, for a given chemical on the basis of existing scientific literature. An RfD is the amount below which human exposure is deemed unlikely to cause adverse health effects. IRIS receives some 2,000 internet visits a day, testament to its importance as among the best, most comprehensive databases for this kind of baseline information. And, although IRIS itself most definitely is not a regulatory program, it provides a strong scientific foundation for much of the rest of the agency's work. Without the scientific determinations IRIS contains, EPA would be hard-pressed to develop standards for the control of emissions of toxic chemicals that cause brain damage, cardiovascular illness, reproductive dysfunction, cancer, and a range of other diseases. Conversely, delaying the production of IRIS profiles costs lives and endangers public health, an intolerable outcome that this Committee must not allow to happen.

My testimony today makes three points:

1. IRIS assessments have once again slowed to a crawl, once again reaching the nadir of performance under the Bush Administration. The Obama Administration needs to stop jawboning with industry stakeholders and support the revitalization of this critical initiative.
2. The highest, best use of the National Academies' expertise would be to help the IRIS program identify ways to develop a significantly larger number of robust assessments *quickly*.
3. To achieve that goal of quickly developed, robust assessments, Congress, the EPA Administrator, and the National Academies must confront the very serious problem of regulated industries commandeering the IRIS assessment process by barraging the agency with endless, minor, repetitive, and irrelevant objections to individual risk assessments.

IRIS and the Public Health

On Thursday, January 9, 2014, a leaking tank of "crude MCHM" (technically, 4-methylcyclohexanemethanol) fouled the Elk River in West Virginia, leaving 300,000 people without access to clean drinking water. The spill prompted a "do not use" order from local officials that was slowly lifted over the course of a week while the water system was flushed to the point where samples dropped below a 1 part-per-million "screening level" proposed by the U.S. Centers for Disease Control (CDC). In an astonishing display of all that is wrong with our country's approach to regulating toxic chemicals, Governor Earl Ray Tomblin told residents of the state capital, "it's your decision" whether to drink water distributed by the local public water system after the "do not use" orders were lifted.

What the Governor was saying – without actually saying it – was, "I have no clue whether the water is safe to drink." He didn't have a clue because crude MCHM is one of the tens of thousands of chemicals that pervade our lives but have not been subject to a robust hazard or risk assessment. The IRIS database has over 500 chemical profiles, but crude MCHM is not one of them.

Crude MCHM's absence from the IRIS database is likely due to the fact that it does not fall squarely within the ambit of EPA's three key statutes for regulating toxic chemicals: the Clean Air Act (CAA), the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), more commonly known as the Superfund law, and the Safe Drinking Water Act (SDWA).¹ The IRIS program operates on a shoestring budget, so its agenda for developing assessments is largely driven by the needs of regulatory offices at EPA. The Office of Air and Radiation, for instance, needs IRIS assessments to fulfill its statutory mandate to write rules for CAA § 112 Hazardous Air Pollutants (HAPs). Congress explicitly listed over 180 chemicals in the 1990 Clean Air Act Amendments for which EPA must set emission standards and then later determine whether those standards adequately control residual risks. IRIS assessments are critical to EPA's work in this area.

This incident, which gives us a frightening glimpse of what life without government could be like, suggests that we need to dramatically expand IRIS, rather than allowing self-interested stakeholders to hound it to death.

Without the scientific determinations IRIS contains, EPA would be hard-pressed to develop standards for the control of emissions of toxic chemicals that cause brain damage, cardiovascular illness, reproductive dysfunction, cancer, and a range of other diseases. IRIS assessments are also invaluable to the decisionmakers involved in cleaning up Superfund sites and brownfields across the United States. As our industrial past makes way for a growing service-sector and knowledge-based economy, and as urban renewal projects sprout up in old cities like Baltimore, Pittsburgh, and Chicago, state regulatory agencies have to make decisions about how to clean up complex contamination. Again, IRIS assessments provide the starting point for making strong, science-based decisions.

The thing that makes IRIS assessments so valuable is that they are robust and well-documented, but then summarized clearly and concisely and available to anyone who has access to the Internet. Individuals, community groups, public interest organizations, local officials – in short, everyone – has the information to make well-informed decisions about the hazards of a toxic chemical if an IRIS profile is available. To go back to Governor Tomblin's infamous statement, "it's your decision" would be a more reasonable response to the end of a "do not use" order in a world where every chemical in commerce has an IRIS assessment. But that is not the world we live in. Delaying the production of IRIS profiles costs lives and endangers public health, an intolerable outcome.

Unfortunately, IRIS is already riddled with disturbing gaps in the data in its chemical profiles, and it is missing profiles for many dangerous chemicals altogether. EPA's efforts to fill IRIS's data gaps were largely stymied during the Bush Administration, and not by accident. The Administration imposed "reforms" designed to subject EPA's scientists – the ones who should be making final decisions on the safety of chemicals – to a host of political pressures from government agencies with neither scientific expertise nor an interest in protecting the environment. The Obama Administration recognized the problem, but its revisions to the IRIS

¹ I consider the Toxic Substances Control Act largely irrelevant to this conversation because of EPA's dismal track record in issuing regulations under § 6 of that statute.

process have left key issues unaddressed and of late it has displayed a disturbing tendency to retreat in the face of a blistering and self-serving industry campaign to stifle this vital program.

EPA is many years behind in completing profiles of hundreds of chemicals. In 2011, we found that 109 HAPs were either included in IRIS but missing critical elements, or entirely absent from the database. So severe are the delays in the IRIS process that they are the principle reason that GAO has determined that EPA's toxic chemical regulatory program is at risk of becoming obsolete. (See GAO's 2013 "High Risk Programs" report at <http://www.gao.gov/assets/660/652133.pdf>.)

For the first year or two, the Obama Administration managed to increase the number of completed profiles to nine annually. At that rate, EPA would not catch up with its existing backlog for another 55 years. But in the last two years, industry attacks on IRIS have been so intense that the pace has once again slowed to Bush levels, giving IRIS the appearance of the walking dead of regulatory program, an outcome that threatens to undermine EPA's effectiveness. One reason for this latest round of malaise is that the Obama Administration's new IRIS process left in place many of the roadblocks GAO had previously identified, including interagency review of individual assessments, multiple reviews by outside science panels, and prioritization of a few high-profile assessments at the expense of faster assessments.

Make no mistake about it: the chemicals we are talking about here are the worst of the worst, produced in amounts of millions of pounds annually. As just one example, chromium compounds, which are categorized in the worst ten percent of all toxic chemicals and are among the hazardous air pollutants missing from IRIS, are emitted in amounts exceeding 58 million pounds annually. Unsafe exposure to chromium compounds causes cancer, suppresses immune systems, and harms kidney and respiratory functions. Over the last several years, industry has sponsored several studies of chromium. When a study documents adverse effects at common levels of exposure, the sponsors commission a second study designed to rip apart the first. Unfortunately, the victims of this endless treadmill are neither the sponsors, nor the scientists engaged in chasing each other's tails, but rather the public's health.

This brings me to my second point.

What the National Academies Can Do for IRIS

From my perspective outside the National Academies, the two committees responsible for the 2011 formaldehyde review and this most recent review of the IRIS process have missed golden opportunities to provide constructive advice on the biggest concern about the IRIS program: how to develop new assessments quickly, on a limited budget. Rather than flyspecking the faults of specific IRIS assessments, and subjecting the program as a whole to highly critical examination, two issues must be addressed to solve this problem: the IRIS program's agenda, and so-called "stopping rules."

Agenda

With my colleagues at the Center for Progressive Reform, I came up with a list a few years ago of all of the Clean Air Act HAPs, Superfund "high priority" substances, and Safe

Drinking Water Act contaminants that did not have IRIS profiles. We found more than 200 individual chemicals, which we consider mission-critical for EPA. To whittle that list down to something more manageable, we proposed an approach that takes environmental justice into account. In our view, the burden on already disadvantaged communities must be a top priority for the nation.

Environmental justice, as defined by EPA, means “fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.”² In practice, EPA’s policy for ensuring environmental justice places an obligation on EPA staff to consider first, whether their actions disproportionately impact any group(s) of people, and second, whether all affected groups have a meaningful opportunity for involvement in the regulatory process.

IRIS staff could take into account the potential for disproportionate impacts by analyzing emissions and exposure data for the unassessed HAPs, Superfund priority chemicals, and drinking water contaminants to determine where clusters of those unassessed chemicals can be found. We made a rudimentary attempt at doing so and were able to identify a handful of communities where polluters release a large diversity of toxic air pollutants and where the emissions include a large number of HAPs without IRIS profiles. We identified 47 chemicals that deserve to be at the top of the IRIS program’s agenda. Our methodology was but one way that IRIS staff might take environmental justice into account when prioritizing new assessments.

Stopping Rules

Once EPA starts an IRIS assessment, there must be an end in sight. An assessment must be declared finished and its results posted on the web. When significant new science is produced suggesting that the numbers must be lowered or raised, EPA can reexamine the profile. Too often, though, regulated industries manage to push EPA on a treadmill where it never escapes the wait for one study or another to be completed before moving forward with a draft assessment. The trouble is, science is always evolving. EPA cannot wait on all the science to resolve itself on the “truth” to be announced—that simply is not the nature of the scientific enterprise. Instead, EPA must adopt clear rules that explain why agency experts have moved to the next stage in the assessment process. The National Academies endorsed stopping rules in the most recent report, but did so without providing sufficient, detailed guidance to EPA. Theoretically, the timelines laid out in the IRIS process flow charts produced at the beginning of the Obama Administration under Administrator Lisa Jackson’s leadership would suffice. But those timelines have ever been enforced. I am not aware of a single assessment that has been completed in the 26 months (for “standard” assessments) or 39 months (for “complex” assessments) contemplated by these commitments.

Given that the science of risk is always evolving, any stopping rule has a degree of arbitrariness to it, but that is not a reason to shy away from setting the rules. The assessment

² ENVIRONMENTAL PROTECTION AGENCY, OFFICE OF POLICY, ECONOMICS AND INNOVATION, EPA’S ACTION DEVELOPMENT PROCESS: INTERIM GUIDANCE ON CONSIDERING ENVIRONMENTAL JUSTICE DURING THE DEVELOPMENT OF AN ACTION (2010) available at <http://epa.gov/compliance/ej/resources/policy/considering-ej-in-rulemaking-guide-07-2010.pdf> (accessed Nov. 2, 2010).

process includes a point at which IRIS staff publish their literature search strategy and results for public comment. One approach to stopping rules would be to use the end of the comment period as the stopping point: if ongoing or recently completed research is not in a form that meets the selection criteria, then it will not be considered. That approach takes into account the critical – but often ignored – fact that IRIS profiles *are not regulations*. The rulemaking process under the CAA and SDWA, as well as decisions about cleanup of contaminated sites, provide numerous opportunities to re-assess the state of the science on a chemical. IRIS assessments are just a starting point.

Industry Influence at IRIS

Stopping rules are an important way to speed up the IRIS process, but they are insufficient to address the larger problem of too much industry influence over the IRIS program.

In recent years, the IRIS program has hosted numerous stakeholder engagement events, some tied to specific assessments, others related to broader science issues or even general concerns about the IRIS program as a whole. However, this openness has obscured the agency's commitment to the protection of public health because EPA senior management's naïve idea that process will placate its critics has left it vulnerable to cynical exploitation by regulated industries.

Take, for example, last month's meeting on the inorganic arsenic and hexavalent chromium assessments. A group of public interest-oriented scientists, led by Dr. Kathleen Burns of the group Sciencecorps, reviewed the agenda for the meeting and found that industry-sponsored speakers filled 37 of the 46 speaking slots during the arsenic meeting and 40 of the 41 slots during the chromium meeting.³ Regular participants in IRIS public forums and related events will confirm a similar imbalance in the public input at those events – with heavy reliance on industry and comparatively less input from environmentalists, community groups, and others without a financial interest in IRIS.

The National Academies made a helpful suggestion on this point that deserves repeating. The committee reviewing the IRIS process noted that:

[non-industry] stakeholders have fewer resources and are not generally organized and staffed to provide comments or detailed scientific input. Thus, their important perspectives and voices might be less well represented to EPA. Therefore, the committee encourages EPA to continue the additional efforts to ensure that the full breadth of perspectives on the IRIS process and specific IRIS assessments are made available to the agency.

One way to ensure broad stakeholder input would be to provide technical assistance to enable under-resourced stakeholders to develop and provide input to the IRIS program; this could be modeled after other EPA technical-assistance programs. For example, EPA's Superfund program has a long history of providing technical assistance in the

³ http://www.sciencecorps.org/Boycott_Statement_to_EPA_re_IAs_&_CrIV_mtg_6-24pm.pdf

form of grants and more recently direct consultation to neighbors of sites on the National Priorities List.⁴

Recognizing the resource constraints under which the IRIS program operates, the proposed technical assistance grants and direct consultation idea deserve thorough consideration. Another idea would be to simply limit the round robins of preliminary meetings, stakeholder listening sessions, and repetitive peer review, instead running the process for crafting an IRIS profile in a far more efficient manner.

Conclusion

Discussions about how the IRIS program can best accomplish its goals often devolve into debates about the minutiae of chemical risk studies. Let us not lose sight of what is really at stake: the priceless notion that the water we drink and the air we breath ought to be clean and healthy.

⁴ NATIONAL RESEARCH COUNCIL OF THE NATIONAL ACADEMIES, *Review of EPA's Integrated Risk Information System (IRIS) Process*, 23 (2014).

Setting Priorities for IRIS:

47 Chemicals that Should Move to the Head of the Risk-Assessment Line

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*Setting Priorities for IRIS: 47 Chemicals that Should Move to
the Head of the Risk-Assessment Line*

Executive Summary

EPA's Integrated Risk Information System (IRIS) is the starting point for new regulations under the Clean Air Act (CAA), Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) and the Safe Drinking Water Act (SDWA). Scientists in the IRIS office produce risk assessments of individual chemicals, which regulatory staff then combine with exposure data and statute-based policy choices to write new emissions limits and cleanup standards. In previous reports, the Center for Progressive Reform (CPR) has described massive gaps in the IRIS database, including more than 250 chemicals for which EPA's air, drinking water, and Superfund offices need robust risk assessments.¹ In this white paper, we describe how EPA should prioritize the work it will take to close those data gaps. We have developed a list of 47 chemicals that IRIS staff should move to the top of its list of priorities, based on the air toxics, drinking water, and Superfund program offices' most pressing needs.

Toxicology is predicated on the axiom that the dose makes the poison. IRIS profiles provide EPA, state and local public health officials, and the public with information about the relevant doses for hundreds of toxic substances. We recommend EPA improve its priority-setting process for IRIS by taking a two-step approach to deciding which data gaps to fill first. As a first step, EPA must foster better cooperation and communication between IRIS staff and their colleagues in the air, drinking water and Superfund program offices, to ensure that the priorities of risk assessors in the IRIS office parallel the priorities of risk managers in the program offices. Second, EPA should take environmental justice into consideration and determine whether there are patterns of unknown chemicals being emitted in large quantities in disadvantaged communities.

¹ CENTER FOR PROGRESSIVE REFORM, *Corrective Lenses for IRIS: Additional Reforms to Improve EPA's Integrated Risk Information System* (Oct. 2010), available at http://www.progressivereform.org/articles/IRIS_1009.pdf [hereinafter CPR, *Corrective Lenses for IRIS*].

Table 1: Priority Chemicals List				
<i>Air toxins</i>	<i>Superfund pollutants</i>	<i>Drinking water contaminants</i>	<i>Multi-media threats</i>	<i>Environmental justice concerns</i>
Cadmium compounds	Polycyclic aromatic hydrocarbons	1,2-Diphenylhydrazine	Acetamide ^{1,3}	1,1,2-Trichloroethane ^{1,2,4,5}
Carbonyl sulfide	Arochlor 1260	1,3-Dinitrobenzene	4-Amino-biphenyl ^{1,2}	1,2-Dichloroethane ^{1,2,3,4}
Formaldehyde	Arochlor 1242	Acetochlor ethanesulfonic acid	Arochlors ^{1,2}	Chlorobenzene ^{4,5}
Hydrogen fluoride	Arochlor 1221	Acetochlor oxanilic acid	Chromium ^{2,3}	Diaminotoluene ⁴
Lead compounds	Cobalt	Alachlor ethanesulfonic acid	Cobalt ^{2,3}	Hexachlorobenzene ^{4,5}
Mercury compounds	DDT, O,P ¹	Alachlor oxanilic acid	Ethylene oxide ^{1,3}	Hexachloroethane ^{1,3,4,5}
Methanol	Nickel	Diazinon	2,3,7,8-Tetrachlorodibenzo-p-dioxin ^{1,2}	Methyl iodide ⁵
Methylene chloride	Endrin ketone	N-Nitroso-dimethylamine (NDMA)	Vanadium ^{2,3}	Phthalic anhydride ^{2,3}
Nickel compounds	Chromium(VI) oxide	N-Nitroso-diethylamine (NDEA)		Quinone ²
Phenol	Methane	N-nitroso-di-n-propylamine (NDPA)		Urethane ³
		Terbufos		

¹Air, ²Superfund,
³Drinking water

Chemicals above are released in the following ZIP codes: ¹70734, ²70805, ³71730, ⁴77541, ⁵77571

In CPR's last paper on IRIS's information gaps, we identified 253 unique substances that need new or updated IRIS assessments.² In this paper, we selected the 47 substances from that list that EPA should move to the front of the line. The IRIS program staff are currently working on new assessments for just 17 of these 47 substances,³ underscoring our concern that statutory priorities are not sufficiently factored into the IRIS agenda. The 47 unique substances listed in

² CPR, *Corrective Lenses for IRIS*, *supra* note 1, at 2-3.

³ ENVIRONMENTAL PROTECTION AGENCY, *Integrated Risk Information System (IRIS): Request for Chemical Substance Nominations for 2011 Program*, 75 Fed. Reg. 63,827 (Oct. 18, 2010).

Table 1 include: ten hazardous air pollutants (HAPs) in the greatest number of upcoming air toxics standards; the ten highest-scoring Superfund priority substances; 11 substances listed on the drinking water Contaminant Candidate List; eight substances that appear on more than one list; and the ten highest-emitting HAPs in areas with environmental justice concerns.

Introduction

EPA's three key statutes for regulating toxic chemicals in commerce are the Clean Air Act (CAA), the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), and the Safe Drinking Water Act (SDWA). These statutes share two characteristics that make environmental regulation complex: they are media-specific, which balkanizes the regulatory landscape; and they require EPA to quantify the risks of individual chemicals before setting regulations.

At present, EPA takes nominations for new chemical risk assessments from Deputy Assistant Administrators, Deputy Regional Administrators, federal agencies that participate in reviews of draft IRIS assessments, and the public, then uses six criteria to select chemicals for IRIS assessments from among the nominations. But this process has not been sufficient to push the IRIS office to complete assessments in time for EPA program offices to regulate toxic substances.

The priority setting process functions like a black box: We know the criteria EPA applies and we know which IRIS profiles are completed, but we do not know how EPA applies these criteria to the un-assessed and under-assessed substances to set IRIS priorities. Based on the large number of chemicals identified by program offices that have not been assessed, we can infer that EPA's current process is not prioritizing assessments to meet the program offices' needs.

In this paper, we propose a two-step process for prioritizing new chemical reviews in the IRIS program: first, risk assessors from the IRIS office and risk managers from the regulatory offices need to work together to develop a complete list of chemicals in need of IRIS assessments; second, the chemicals should be prioritized in terms of the existing regulatory agenda and environmental justice concerns.

EPA program offices provide public information about chemicals considered for regulation, which we have parsed to develop a list of 253 substances that could be the starting point for discussions between IRIS risk assessors and regulatory risk managers. The CAA HAPs have been public since the Clean Air Act Amendments of 1990 were made law; the Agency for Toxic Substances and Disease Registry (ATSDR), a program under CERCLA, periodically publishes a list of priority chemicals; and, under the SDWA, the Office of Water must publish a Contaminant Candidate List (CCL) every five years. This information gives the IRIS staff guidance about chemicals of concern to EPA, but does not help them to prioritize their work.

Since IRIS staff cannot tackle all 253 substances at once, a more robust effort at coordination is necessary, including regular meetings between the staff and managers of all offices to set short- and long-term priorities. Those priorities should be informed by environmental justice concerns. Specifically, EPA should prioritize the assessment of chemicals that lack IRIS profiles and are emitted in large quantities in communities with significant populations of poor and minority residents and in localities where a large number of un-assessed chemicals are emitted together. In this white paper, we profile five communities that bear the burden of numerous un-assessed HAPs and multiple Superfund sites.

Improving priority-setting policies will put the IRIS staff on the right path, but the database will remain outdated without reforms to the assessment process. Potentially regulated parties, particularly industry and other federal agencies like the Department of Defense and National Aeronautics and Space Administration, have isolated IRIS as a choke point for regulation. Their opposition has resulted in an IRIS program that can neither keep up with the demands that have already been made, nor incorporate information about new substances. IRIS staff must consider new ways to avoid the problem of “information capture,” whereby potentially regulated parties dump so much new data on the agency – and do so with such frequency – that new assessments become mired in continuous controversy.

Setting Priorities, Step One: Improving Communication between Regulatory Office and IRIS Staff

EPA program offices have specific deadlines and plans to complete regulatory actions on toxic chemicals. The IRIS staff should be well-attuned to the deadlines and priorities of the program offices, and strive to provide program offices with the best available risk assessment information in a timely manner to support regulatory decisions. There should be regular communication and interaction between the program office staff and IRIS staff to facilitate priority-setting and ensure that priorities are consistent with the needs of the program offices.

The next three sections provide some additional details about the three programs and some thoughts on prioritizing chemicals that are important to each program.

Hazardous Air Pollutants

The CAA Amendments of 1990 specify 188 toxic air pollutants that EPA must regulate through a two-step process. First, EPA must issue “technology-based” standards for all major sources of HAPs. At this stage, EPA staff simply determine emissions limitations based on the average emission limitation of the best performing 12 percent of existing sources. EPA has issued 96

technology standards covering 174 “major” and “area” sources.⁴ In the second step of the HAPs regulations, EPA must evaluate “residual risks” associated with air pollutants eight years after the technology-based standards are promulgated, in an effort to determine whether the technology-based standards protect public health with “an ample margin of safety.”⁵

IRIS profiles are integral to the residual risk determinations. EPA considers an ample margin of safety to be exposures below the reference concentration (RfC or inhalation value) listed in IRIS for non-carcinogens, and the level at which added cancer risk does not exceed one in one million.⁶ But the IRIS database is missing assessments or inhalation values for 107 of 188 HAPs, slowing progress toward completion of residual risk standards. In fact, EPA’s Science Advisory Board (SAB) reviewed the Office of Air and Radiation’s (OAR) methodology for completing two residual risk evaluations and implored EPA to complete IRIS profiles for all HAPs in a timelier manner.⁷ They said that EPA’s alternate method of determining risk was too simplistic, and recommended that EPA elaborate on the proposed method. But they stressed that the best course of action was to complete IRIS profiles for all the HAPs.

Data gaps in IRIS’s HAPs coverage stymie public health efforts led by state and local agencies, too. In 2005, the Mayor of Houston, Bill White, ordered a task force on air pollution in the area. Houston’s Ship Channel is home to large number of petrochemical refineries and other chemical plants, and has high concentrations of a broad range of HAPs. The Task Force focused on 176 HAPs listed in EPA’s 1999 National Air Toxics Assessment that were present in the 10 counties that comprise the greater Houston area. The researchers expressed difficulty in developing risk characterizations for Houston-area HAPs: “The intrinsic challenges of comparing HAPs-related health risks are illustrated by the fact that 118 (67%) of the 176 HAPs examined by the Task Force were assigned to the uncertain risk category. This decision was based on their collective judgment that there is insufficient evidence on hand to ascertain whether these substances currently pose a significant threat to the health and well being of Houston residents.” Of the 118 HAPs placed in the uncertain risk category, 63 are missing IRIS profiles or lack inhalation values.

EPA completed the last of the technology-based standards in 2006, so it must issue all residual risk standards by 2014. With that deadline in mind, and with input from OAR, IRIS staff should set an agenda for completing risk assessments on all HAPs in an order that will pave the way for

⁴ ENVIRONMENTAL PROTECTION AGENCY, OFFICE OF INSPECTOR GENERAL, EVALUATION REPORT: KEY ACTIVITIES IN EPA’S INTEGRATED URBAN AIR TOXICS STRATEGY REMAIN UNIMPLEMENTED, Report No. 10-P-0154, (2010).

⁵ 42 U.S.C. § 7412(f).

⁶ See, e.g., ENVIRONMENTAL PROTECTION AGENCY, *National Emission Standards for Coke Oven Batteries*, 70 Fed. Reg. 19,993 (Apr. 15, 2005).

⁷ ENVIRONMENTAL PROTECTION AGENCY, SCIENCE ADVISORY BOARD. *Review of EPA’s draft entitled, “Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA’s Science Advisory Board with Case Studies – MACT I Petroleum Refining Sources and Portland Cement Manufacturing,”* SAB-10-007, at 5 (May 7, 2010) [hereinafter EPA, *RTR Methodology*].

OAR's regulatory agenda. EPA has already finalized 16 residual risk standards and proposed or requested comment on 17 others. IRIS and OAR staff should work together to determine how the 13 HAPs covered by proposed standards but lacking key IRIS data could be assessed in time to meet OAR's regulatory timeline. A recent consent decree prompted by a Sierra Club lawsuit sets deadlines for 16 more residual risk standards that cover 114 HAPs—43 of which lack inhalation values in the IRIS database and should also be prioritized for review by IRIS staff.

CPR reviewed EPA's proposed rules and the 16 other standards which EPA must propose under the consent decree, and identified 123 HAPs in these upcoming standards.⁸ Table 2 highlights the top 10 of those 123 HAPs, based on the number of upcoming rules in which they appear. The Appendix (Table A2) provides a longer list—all 46 HAPs that appear in upcoming standards but lack inhalation values or do not have IRIS values. Input from OAR would be valuable in improving the usefulness of this priority list. OAR needs IRIS profiles for HAPs to complete the residual risk standards, and OAR should share its needs with ORD, so IRIS profiles can be completed in a timely manner.

Table 2: Hazardous Air Pollutants with Insufficient IRIS Information in Upcoming Residual Risk Rules	
Chemical	<p><i>Human Health Effects: Cadmium compounds</i></p> <p>Cadmium compounds have been linked to kidney disease, lung damage, cancer, and fragile bones.</p> <p>AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, ToxFAQ for CADMIUM, (Sept. 2008), available at http://www.atsdr.cdc.gov/toxfaq5.pdf (accessed Oct. 21, 2010).</p>
Cadmium compounds*	
Carbonyl sulfide	
Formaldehyde	
Hydrogen fluoride*	
Lead compounds	
Mercury compounds	
Methanol	
Methylene chloride	
Nickel compounds	
Phenol	
* No IRIS profile information.	

⁸ ENVIRONMENTAL PROTECTION AGENCY, *Risk and Technology Review, Phase II, Group 2*, 72 Fed. Reg. 14,741-14,744 (Mar. 29, 2007); ENVIRONMENTAL PROTECTION AGENCY, *National Emission Standards for Hazardous Air Pollutant Emissions: Group I Polymers and Resins*, 73 Fed. Reg. 60,437-60,440 (Oct. 8, 2008).

Superfund Pollutants

Superfund is a critical part of EPA's overall mission. The Superfund program has a budget of \$1.3 billion; it makes up 12 percent of EPA's total budget.⁹ Cleanup standards for Superfund inform other waste management programs, including the Resource Conservation and Recovery Act and private-sector cleanup efforts. IRIS profiles are the first step in setting Superfund standards and initiating work that radiates beyond Superfund.

Superfund sites are places of significant soil and groundwater pollution, often by multiple contaminants. EPA prioritizes cleanup efforts based on whether contaminants pose an immediate hazard or a longer-term cleanup effort. Sites that are not marked for emergency response are added to the National Priorities List (NPL). After a site has been added to the NPL, it undergoes a seven-step process through which EPA oversees the remediation of a site, a process that begins with risk assessment.

The CERCLA requires ATSDR to periodically compile a list of "high priority" substances.¹⁰ ATSDR generates this list from substances that are found in sites on the NPL. The list is placed in a weighted priority order that takes into account the frequency with which substances are found at sites on the NPL, the toxicity of the substance, and the likelihood of human exposure to the substance at a site. ATSDR provides the IRIS staff with quite a bit of useful information to make determinations about how to prioritize substances for IRIS assessment. ATSDR updates the list periodically, with new substances being added and others removed as the sites on the NPL change.¹¹ Nonetheless, many substances remain on the list for years, because they are common industrial chemicals, or are persistent environmental toxics. Even the longstanding high priority chemicals lack sufficient coverage in IRIS – 17 substances that have been on ATSDR's list since 1997 do not have IRIS profiles (See Appendix, Table A4).

Why ATSDR?

Dividing responsibilities across multiple agencies is one strategy to avoid agency capture. Congress created the ATSDR in 1986, after the integrity of EPA's Superfund program had been called into question by the actions of Reagan administration officials in charge of the program.

ATSDR's list, like the CAA's list of HAPs, provides an obvious indication of an EPA regulatory office's needs. But similar to its treatment of HAPs data gaps, EPA's IRIS agenda does not explain how it will address data gaps for substances on the ATSDR high priority list. There is no formal relationship between the ATSDR list and the IRIS agenda process. Research conducted

⁹ ENVIRONMENTAL PROTECTION AGENCY, FY 2010 EPA BUDGET IN BRIEF, 2, 6 (Apr. 2009) available at <http://www.epa.gov/budget/2010/2010bib.pdf> (accessed Dec. 15, 2010).

¹⁰ 42 U.S.C. § 9604(i).

¹¹ AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, CERCLA PRIORITY LIST OF HAZARDOUS SUBSTANCES, lists are available for 1997, 1999, 2001, 2003, 2005 and 2007, available at <http://www.atsdr.cdc.gov/cercla/07list.html> (accessed Sept. 16, 2010) [hereinafter ATSDR, CERCLA PRIORITY LIST].

by ATSDR should flow freely between ATSDR and the IRIS program – indeed IRIS was created when EPA combined several disparate databases of human health information maintained by various program offices at EPA. The Superfund program should support IRIS to the extent that ATSDR is able to assist the IRIS program in completing assessments, identifying key studies, and making judgments about weight-of-the-evidence evaluations of toxic chemicals.

Table 3: Top Ten ATSDR Priority Chemicals not Listed in IRIS¹²		<i>Human Health Effects: Nickel</i>
<i>Chemical</i>	<i>ATSDR points¹³</i>	
Polycyclic aromatic hydrocarbons	1316.98	<p>Exposure to nickel dust has been linked to respiratory problems including bronchitis and reduced lung function. Occupational exposures have been linked to lung and nasal cancer.</p> <p>AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, TOXFAQ FOR NICKEL, (Aug. 2005), available at http://www.atsdr.cdc.gov/toxfaq15.pdf (accessed Oct. 21, 2010).</p>
Aroclor 1260	1177.77	
Aroclor 1242	1093.14	
Aroclor 1221	1018.41	
Cobalt	1015.57	
DDT, O,P'	1014.71	
Nickel	1005.4	
Endrin ketone	978.99	
Chromium(VI)oxide	969.58	
Methane	959.78	

Drinking Water Contaminants

The Safe Drinking Water Act (SDWA) requires EPA to set standards for limits on drinking water contaminants. Unlike HAPs, which were specified by Congress, EPA is responsible for identifying water contaminants. EPA identifies additional water contaminants that might be candidates for regulation every five years by generating a new Contaminant Candidate List (CCL).¹⁴ The lists contain recommendations both for chemicals and microbiological contaminants. Since 1996, EPA has published three CCLs that contain 156 distinct chemical substances.¹⁵ IRIS profiles are missing for 64 (41 percent) of these substances. Absence of an IRIS profile hinders regulation of drinking water contaminants because the Water Office uses health risk information to prioritize unregulated substances to monitor, as well as determine what order to regulate water contaminants.

¹² ATSDR, CERCLA PRIORITY LIST, *supra* note 11.

¹³ Points are assigned by ATSDR is based on an algorithm that utilizes the following three components: frequency of occurrence at NPL sites, toxicity, and potential for human exposure to the substances found at NPL sites. See AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, CERCLA PRIORITY LIST OF HAZARDOUS SUBSTANCES, WHAT IS THE CERCLA LIST, available at <http://www.atsdr.cdc.gov/cercla/index.asp> (accessed Sept. 19, 2010) [hereinafter ATSDR, WHAT IS THE CERCLA LIST].

¹⁴ 42 U.S.C. § 300g-1(b)(1)(B)(i).

¹⁵ ENVIRONMENTAL PROTECTION AGENCY, *Announcement of the Drinking Water Contaminant Candidate List*; Notice, 63 Fed. Reg. 10,273 (Mar. 2, 1998); ENVIRONMENTAL PROTECTION AGENCY, *Drinking Water Contaminant Candidate List 2*; Final Notice, 70 Fed. Reg. 9,071 (Feb. 24, 2005); ENVIRONMENTAL PROTECTION AGENCY, *Drinking Water Contaminant Candidate List 3 – Final*, 74 Fed. Reg. 51,850 (Oct. 8, 2009).

The SDWA requires the EPA Administrator to make a public health finding about a contaminant before EPA moves to regulate the substance. The public health finding requires three determinations: first, EPA must establish that the contaminant may have an adverse effect on human health; second, the agency must determine that the contaminant is known or likely to occur in public water systems; and third, EPA must determine that regulation through SDWA presents a meaningful opportunity for reducing public health risks.¹⁶ Reference doses contained in IRIS profiles are exactly relevant to the first determination. The IRIS program has not kept up with demand to provide information about CCL substances, which makes it more difficult for EPA to make the health risk related determinations required under SDWA.

Table 4 lists 11 of the 64 substances that appear in the CCLs that do not have IRIS profiles, culled from the larger list because they are also tracked under the Unregulated Contaminant Monitoring program. In the Appendix (Table A5), we identify nine additional substances EPA tracks under the Unregulated Contaminant Monitoring program that do not appear on the Contaminant Candidate Lists, but are missing IRIS profiles.

Table 4: UCMR Listed Substances also on CCL without IRIS profiles	<i>Human Health Effects: Ethylene Oxide</i>
<i>Chemical</i>	Ethylene oxide has been linked to miscarriage, respiratory and nervous system effects.
1,2-diphenylhydrazine	Ethylene oxide is listed of programmatic importance both for safe drinking water and as a HAP.
1,3-Dinitrobenzene	AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, ToxFAQ FOR ETHYLENE OXIDE, (Jul. 1999), available at http://www.atsdr.cdc.gov/tfacts137.pdf (accessed Oct. 21, 2010).
Acetochlor ethanesulfonic acid	
Acetochlor oxanilic acid	
Alachlor ethanesulfonic acid	
Alachlor oxanilic acid	
Diazinon	
N-nitrosodiethylamine (NDEA)	
N-nitrosodimethylamine (NDMA)	
N-nitroso-di-n-propylamine (NDPA)	
Terbufos	

¹⁶ 42 U.S.C. §300g-1(b)(1)(A).

Setting Priorities, Step Two: Considering Environmental Justice

IRIS staff can use the regulatory offices' legal obligations and administrative priorities to start the process of choosing which chemicals need new or updated assessments, but those two factors will still leave them with a substantial list. IRIS staff should further prioritize new assessments by taking into consideration environmental justice concerns.

Environmental justice, as defined by EPA, means "fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies."¹⁷ In practice, EPA's policy for ensuring environmental justice places an obligation on EPA staff to consider first, whether their actions disproportionately impact any group(s) of people, and second, whether all affected groups have a meaningful opportunity for involvement in the regulatory process.

In the IRIS assessment priority-setting context, IRIS staff could take into account the potential for disproportionate impacts by analyzing emissions and exposure data for the unassessed HAPs, CERCLA priority chemicals, and drinking water contaminants to determine where clusters of those unassessed chemicals can be found. Over the next few pages, we profile five communities where HAPs that have insufficient profiles are released in significant quantities. These five communities were chosen because they are sites with a large diversity of toxic air pollutants and have the largest number of HAPs without IRIS profiles. In addition to considering HAPs, we also looked at the presence of Superfund sites, and toxic chemical releases listed in EPA's Toxic Release Inventory (TRI). After we selected the communities, we probed basic demographic information from the 2000 Census, which is listed in the community profiles.

Our methodology is but one way that IRIS staff might take environmental justice into account when prioritizing new assessments. These communities are subject to diverse exposure to toxic chemicals through multiple pathways. We selected them based on the presence of the largest number of exposures to substances that are missing IRIS profiles, but these communities are also exposed to an even larger diversity of toxins.

One of EPA's long-term goals is to better understand the cumulative impacts of multiple toxins.¹⁸ Chemical-by-chemical information contained in IRIS – oral exposure limits, inhalation values – is exactly the kind of toxicology information needed to complete cumulative risk

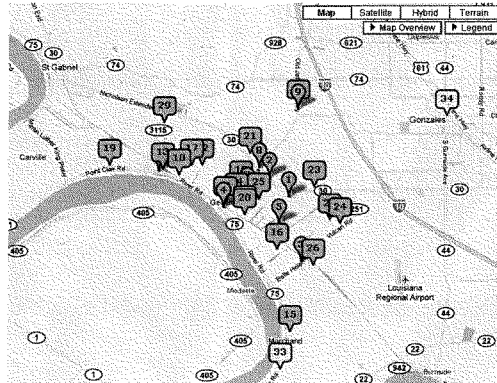
¹⁷ ENVIRONMENTAL PROTECTION AGENCY, OFFICE OF POLICY, ECONOMICS AND INNOVATION, EPA'S ACTION DEVELOPMENT PROCESS: INTERIM GUIDANCE ON CONSIDERING ENVIRONMENTAL JUSTICE DURING THE DEVELOPMENT OF AN ACTION (2010) available at <http://epa.gov/compliance/ej/resources/policy/considering-ej-in-rulemaking-guide-07-2010.pdf> (accessed Nov. 2, 2010).

¹⁸ See, e.g., Thomas Burke, *Overview of Cumulative Risk, presentation before Environmental Protection Agency, Mid-Atlantic Cumulative Risk Workshop* (2003), available at http://www.epa.gov/region3/environmental_justice/cumriskwshop.htm (accessed Dec. 1, 2010).

analysis. Cumulative risk assessments are highly dependent on toxicology information about each of the various toxic substances and exposure pathways. If toxicology information is not present, then the evaluation cannot be credibly completed. Cumulative risk assessments become less credible as the number of data gaps increase. EPA must identify both where there is a large diversity of exposure to toxic substances, and which toxic substances that appear in these areas are missing critical toxicology information. The IRIS office should then strive to prioritize substances that hinder cumulative risk assessment.

EPA's environmental justice policies also require that staff consider whether all affected groups are able to meaningfully participate in program decisions. IRIS staff can help more groups participate more meaningfully in the regulatory process by finalizing new chemical profiles for toxins that appear in communities like those profiled below. These communities often have limited resources to devote to participation in the highly technical standard-setting and permitting decisions that affect the quality of their air, water, and soil. The existence of IRIS profiles for all relevant chemicals helps these communities advocate for themselves. The IRIS office should strive to support environmental justice by identifying unassessed chemicals from our list that appear in communities that are not adequately included in the decision making process.

Geismer, LA 70734
Ascension Parish



Geismer, Louisiana is located about 30 miles south of Baton Rouge. It is home to a large number of petrochemical facilities, including the largest manufacturing facility for the chemical company BASF. According to EPA's Toxic Release Inventory, residents of Geismer are exposed to 94 toxic chemicals.

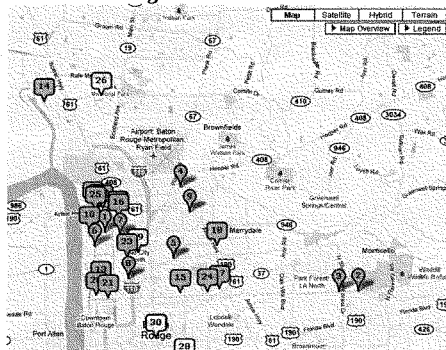
Blue markers represent sources of air pollution. Yellow markers are Superfund sites.

Toxics Release Inventory Information for 70734				
Total Releases (lbs)	Air Releases (lbs)	Water Releases (lbs)	Land Releases (lbs)	Transfers to Off-Site Treatment Works (lbs)
9,522,750	2,530,641	6,738,084	27,569	226,457

Sources of Toxic Substance Exposures for 70734 and Ascension Parish		
Air toxics not in IRIS	Superfund sites (70734)	Superfund sites (Ascension, LA)
14	2	5

Demographics Information for Geismer and Ascension Parish		
	70734	Ascension Parish
Race		
White	58.7%	77.6%
Black	36.9%	19.8%
Native American	0.0%	0.4%
Asian	1.6%	0.4%
Pacific Islander	0.0%	0.0%
Hispanic/Other	0.4%	0.9%
Median household income	\$39,336	\$44,288
% below poverty line	12.9%	12.8%

Baton Rouge, LA 70734
East Baton Rouge Parish



Baton Rouge is the capital of Louisiana. It lies on the Mississippi River, about eighty miles west of New Orleans. Baton Rouge is home to a deepwater port connecting the Mississippi River to the Gulf of Mexico. Major industries in Baton Rouge include petrochemical production, plastic, rubber, and timber and paper products, which contribute to air and water pollution in the area. According to EPA's Toxics Release Inventory, residents of Baton Rouge are exposed to 116 different toxic chemicals.

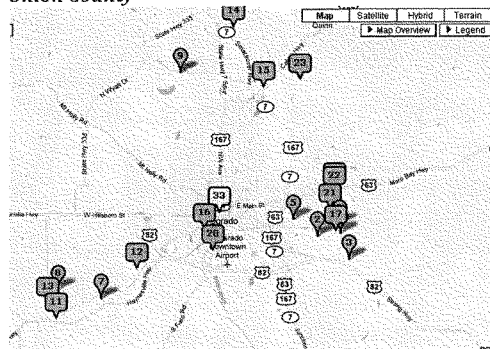
Blue markers represent sources of air pollution. Yellow markers are Superfund sites.

Toxics Release Inventory Information for 70805				
Total Releases (lbs)	Air Releases (lbs)	Water Releases (lbs)	Land Releases (lbs)	Transfers to Off-Site Treatment Works (lbs)
9,961,982	4,725,250	5,089,631	250	146,851

Sources of Toxic Substance Exposures for 70805 and East Baton Rouge Parish		
Air toxics not in IRIS	Superfund sites (70805)	Superfund sites (East Baton Rouge Parish)
12	1	18

Demographics Information for Baton Rouge and East Baton Rouge Parish		
	70805	East Baton Rouge Parish
Race		
White	10.7%	51.8%
Black	86.8%	44.5%
Native American	0.2%	0.3%
Asian	0.8%	2.5%
Pacific Islander	0.0%	0.0%
Hispanic/Other	0.5%	2.8%
Median household income	\$21,203	\$42,173
% below poverty line	34.2%	17.6%

El Dorado, AR 71730
Union County



El Dorado, Arkansas is located in the southern part of the state, near the Louisiana border. It was once a site for oil extraction. More recently it is the home to a diversity of chemicals manufacturing, including agricultural chemicals, automotive chemicals, pesticides, bleaching agents and synthetic dyes. The town of El Dorado contains six Superfund sites. EPA estimates residents of El Dorado are exposed to 177 toxic chemicals.

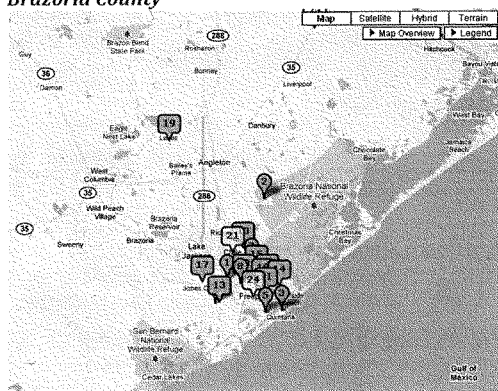
Blue markers represent sources of air pollution. Yellow markers are Superfund sites.

Toxics Release Inventory Information for 71730				
Total Releases (lbs)	Air Releases (lbs)	Water Releases (lbs)	Land Releases (lbs)	Transfers to Off-Site Treatment Works (lbs)
7,749,243	1,209,550	4,369,657	1,464,241	705,794

Sources of Toxic Substance Exposures for 71730 and Union County		
Air toxics not in IRIS	Superfund sites (71730)	Superfund sites (Union County)
14	6	7

Demographics Information for El Dorado, AR and Union County		
	71730	Union County
Race		
White	66.2%	64.8%
Black	31.6%	33.1%
Native American	0.3%	0.3%
Asian	0.4%	2.5%
Pacific Islander	0.0%	0.0%
Hispanic/Other	0.5%	2.8%
Median household income	\$30,565	\$37,120
% below poverty line	18.8%	18.6%

Freeport, TX 77541
Brazoria County



Freeport, Texas is located on the Gulf of Mexico coast south of Houston. It is home to a deepwater port and large-scale petrochemical manufacturing. Freeport also maintains a liquefied natural gas terminal. These sites are major sources of air pollution in Freeport. EPA reports that residents of Freeport are exposed to 136 toxic chemicals.

Blue markers represent sources of air pollution. Yellow markers are Superfund sites.

Toxics Release Inventory Information for 77541				
Total Releases (lbs)	Air Releases (lbs)	Water Releases (lbs)	Land Releases (lbs)	Transfers to Off-Site Treatment Works (lbs)
5,377,060	2,452,712	2,535,381	69,489	319,470

Sources of Toxic Substance Exposures for 77541 and Brazoria County		
Air toxics not in IRIS	Superfund sites (77541)	Superfund sites (Brazoria County)
9	2	10

Demographics Information for Freeport, TX and Brazoria County		
	77541	Brazoria County
Race		
White	83.5%	82.2%
Black	12.1%	11.2%
Native American	0.6%	0.6%
Asian	0.4%	4.6%
Pacific Islander	0.0%	0.0%
Hispanic/Other	19.8%	2.1%
Median household income	\$33,933	\$60,784
% below poverty line	23.5%	9.2%

La Porte, TX 77571
Harris County



Blue markers represent sources of air pollution. Yellow markers are Superfund sites.

LaPorte, Texas is on Galveston Bay and is located in Houston's Ship Channel, which is home to a large number of petrochemical facilities. In 2005, the Mayor of Houston ordered a task force to investigate the effects of air pollution in the Houston area, including Harris County. Data gaps in IRIS hindered the task force's ability to assess health effects. In addition to air pollution, Harris County also contains 81 Superfund sites. According to EPA, residents of LaPorte are exposed to 279 toxic chemicals.

Toxics Release Inventory Information for 77571				
Total Releases (lbs)	Air Releases (lbs)	Water Releases (lbs)	Land Releases (lbs)	Transfers to Off-Site Treatment Works (lbs)
4,379,416	2,195,039	1,680,546	169,558	334,272

Sources of Toxic Substance Exposures for 77571 and Harris County		
Air toxics not in IRIS	Superfund sites (77571)	Superfund sites (Harris County)
16	1	81

Demographics Information for LaPorte, TX and Harris County		
	77571	Harris County
Race		
White	81.5%	73.5%
Black	6.7%	18.7%
Native American	0.6%	0.7%
Asian	0.7%	5.1%
Pacific Islander	0.0%	0.2%
Hispanic/Other	7.9%	1.3%
Median household income	\$56,552	\$42,598
% below poverty line	7.2%	15.9%

Streamlining the Process

Improving the priority-setting process for completing IRIS assessments is key to bringing the IRIS database up to date. But considering that EPA has such a large number of assessments to complete, it must also address how it manages its workload, and devise a process that allows the IRIS program to complete more assessments each year. EPA should streamline the process by setting goals for how many assessments to complete each year, drawing from substances of programmatic importance; eliminating the interagency review process; relying on outside science review only in the most complex cases; and preventing a few high-profile assessments from impeding progress on others by completing those assessments on a separate track with a separate budget.

In addition to structural problems with the IRIS process, regulatory agencies including EPA are plagued by information overload.¹⁹ The regulatory process does not discourage—and actually encourages—interested parties to submit large volumes of unfiltered information to agencies. As a result, attention, not information, is in short supply in making regulatory decisions. The consequences of this overload of information include an increased cost of participation in the regulatory process – both to produce competing analyses and information and to review and understand information submitted by other interests. Industry interests, having more resources to participate in this process, dominate the process in terms of the amount of information submitted to agencies and critical evaluation of information submitted by other interests. This creates an echo chamber effect where agencies hear one perspective—industry’s—much more often than others, creating a perception that the dominant perspective is the correct one.

This drop-off in pluralistic participation is described as “information capture.”²⁰ By volume and frequency of participation, better-funded industry interests influence agencies in favor of the industry position. The IRIS program is subject to substantial information capture due to the complexity of the assessment process and the highly technical nature of its work. The IRIS office faces a prodigious backlog of assessments, and a stream of critique of its work. Industry has a strong incentive to flood the agency with more information than it can effectively process. Since there are no mechanisms in the regulatory process to limit interested parties from dumping raw data into the record, there is too much information for agency staff to read through. The agencies, battered by searching judicial review of their prior decisions, take it upon themselves to respond to the content of all the submissions made to the agency in the course of the regulatory process, in an attempt to insulate themselves against future litigation.

Although the IRIS process is not a regulatory process, it is subject to many of the same challenges in terms of information overload. ORD staff is inundated from the start with

¹⁹ Wendy Wagner, *Administrative Law, Filter Failure, and Information Capture*, DUKE L. J. Vol. 59, (2010) [hereinafter Wagner, *Filter Failure*].

²⁰ *Id.*

information. Before a draft assessment is published, ORD staff comb through the literature and produce a “screening-level literature review,” which is then published in the *Federal Register* and opened for public comment. Industry and other interests, including other federal agencies, then submit additional studies and data that ORD staff must read and synthesize. Part of this process is motivated by industry’s efforts to generate the appearance of controversy, a deregulatory tactic that dates from the tobacco industry’s 1960s efforts to suppress and obfuscate the relationship between smoking and cancer.²¹

Information capture is not unique to the IRIS process. But with such a large backlog of assessments to complete, the IRIS process could be a good test case for strategies to reduce the influence of excessive information. Placing some manner of filtering requirement on interest groups, akin to limits placed by appellate courts on litigants, could provide some relief to agencies in addressing information overload.²² Limits would encourage interested parties to point to specific studies or findings relevant to issues with IRIS assessments. EPA staff could then focus on a few problems and more quickly finish the weight-of-the-evidence determinations required for IRIS.

Conclusion

CPR’s research has identified 253 substances awaiting IRIS assessments, an unacceptably high number. EPA’s program offices need IRIS information to complete statutorily mandated tasks. EPA should set a goal for working through these assessments, and then submit a budget proposal that reflects the resources it would take to finish the work in that amount of time. Congress should then provide the IRIS program with adequate funding to complete the work. Although the current budget situation is such that many programs are being cut, our own back-of-the-envelope calculations estimate that the IRIS backlog could be cleared in five years for approximately \$100 million. In the context of the federal budget, this is not an unbearable request. Indeed, it would amount to 0.003 percent of the \$3.5 trillion in federal outlays from FY2009. The IRIS process should be reformed to remove roadblocks and reduce the amount of time it takes to complete assessments.

Moving forward, EPA should set priorities based on program office need, taking into consideration environmental justice factors. Some mechanism for setting the IRIS agenda based on expected needs of the program offices should be developed. The IRIS staff should determine how many assessments must be completed based on the need from the program offices, not based on the available budget. To the greatest extent feasible, program offices should give ORD advance notice of chemicals of interest, so the IRIS staff can integrate these substances into the

²¹ DAVID MICHAELS, *DOUBT IS THEIR PRODUCT: HOW INDUSTRY’S ASSAULT ON SCIENCE THREATENS YOUR HEALTH* (OXFORD UNIVERSITY PRESS) (2008).

²² Wagner, *Filter Failure*, *supra* note 19, at 1419.

agenda-setting process. EPA should analyze whether certain communities are disproportionately affected by chemicals for which there is no IRIS information and strive to prioritize these assessments as well.

IRIS should push the regulatory agencies forward. It should also screen the epidemiology literature for candidate substances and provide information that prods the program offices to act under statutory authority. The relationship between the program offices and IRIS should be symbiotic and reinforcing.

**Appendix: Additional Tables of Chemicals Indicated by Program Offices
Not Listed in IRIS**

Table A1: Substances identified by CPR as CAA, SDWA, or Superfund data gaps that are being assessed by IRIS staff
<i>Chemical</i>
Aroclors (polychlorinated biphenyls) ^{1,2}
Cadmium ¹
Carbonyl sulfide ¹
Chloroform ¹
Cobalt ^{2,3}
1,2-Dichloroethane ¹
1,4-Dioxane ¹
Ethylene oxide ^{1,3}
Formaldehyde ¹
Methanol ¹
Methyl <i>tert</i> -butyl ether ³
Methylene chloride ¹
Nickel ²
Polycyclic aromatic hydrocarbons ²
2,3,7,8-Tetrachlorodibenzo-p-dioxin ^{1,2}
Tetrachloroethylene ¹
Trichloroethylene ¹
¹ Air pollutants; ² Superfund pollutants; ³ Drinking water contaminants

Table A2: Hazardous Air Pollutants with Insufficient IRIS Information in Proposed or Mandated Residual Risk Rules	
Chemical	
Benzyl chloride	Hexachlorobenzene
Bis(chloromethyl) ether	Hexachloroethane
Bromoform	Hydrogen fluoride
Cadmium compounds	Isophorone
Carbonyl sulfide	Lead compounds
Chlorine	Lindane
Chlorobenzene	Mercury compounds
Chloroform	Methanol
Chloromethyl methyl ether	Methyl iodide
Cyanide compounds	Methyl isothiocyanate
2,4-D	N,N-Dimethylaniline
Dibenzofuran	Nickel compounds
1,2-Dichloroethane	o-Toluidine
Dichloromethane	Pentachloronitrobenzene
Diethyl sulfate	Phenol
Dimethyl carbamoyl chloride	Selenium
2,4-Dinitrophenol	Styrene oxide
2,4-Dinitrotoluene	1,1,2,2-Tetrachloroethane
1,4-Dioxane	Tetrachloroethylene
Dioxin and dioxin-like compounds	1,2,4-Trichlorobenzene
Ethyl acrylate	Trichloroethylene
Ethylene oxide	2,4,5-Trichlorophenol
Formaldehyde	2,4,6-Trichlorophenol

Table A3: Hazardous Air Pollutants with Insufficient IRIS Information in the Hazardous Organic NESHAP

<i>Chemical</i>
Anthraquinone
Bromonaphthalene
Chloronaphthalene
Chrystene
Fluoranthene
Alpha-Naphthalene sulfonic acid
Beta-Naphthalene sulfonic acid
Alpha-Naphthol
Beta-Naphthol
Naphthol sulfonic acid
1-Naphthylamine
2-Naphthylamine
1,4-Naphthylamine sulfonic acid
1,2-Naphthylamine sulfonic acid
1-Nitronaphthalene
Tetrahydronaphthalene

These chemicals are not listed in the Clean Air Act Amendments of 1990 with the other HAPs profiled in this paper, but they were regulated by EPA under the Hazardous Organic NESHAP. We have included them because there is also insufficient IRIS information on these chemicals.

Table A4: ATSDR Priority Chemicals Listed for more than 10 years not in IRIS²³

<i>Chemical</i>	<i>ATSDR points²⁴</i>
Aroclor 1240	888.11
Radon-220	804.54
Tributyltin	802.61
Neptunium-237	802.13
Iodine-129	801.64
Gamma-chlordene	702.59
Americium	701.62
Carbon Monoxide	684.49
Chromium trioxide	610.85
Benzopyrene	603.00
Actinium-227	602.57
Ethoprop	602.13
Alpha-chlordene	601.94
Calcium arsenate	601.48
Hydrogen fluoride	588.03
Pentaerythritol tetranitrate	545.59
Carbazole	534.52

²³ ATSDR, CERCLA PRIORITY LIST, *supra* note 11.

²⁴ Points are assigned by ATSDR is based on an algorithm that utilizes the following three components: frequency of occurrence at NPL sites, toxicity, and potential for human exposure to the substances found at NPL sites. See ATSDR, WHAT IS THE CERCLA LIST, *supra* note 13.

Table A5: Water Contaminants Tracked under Unregulated Contaminant Monitoring, not in the CCL lists, not in IRIS
<i>Chemical</i>
2,2',4,4',5,5'-Hexabromobiphenyl
2,2,4,4',6-Pentabromodiphenyl ether
Dacthal di-acid degradate
Dacthal mono-acid degradate
Lead-210
Metolachlor ethane sulfonic acid
Metolachlor oxanilic acid
Polonium-210
Terbufos sulfone

About the Center for Progressive Reform

Founded in 2002, the Center for Progressive Reform is a 501(c)(3) nonprofit research and educational organization comprising a network of scholars across the nation dedicated to protecting health, safety, and the environment through analysis and commentary. CPR believes sensible safeguards in these areas serve important shared values, including doing the best we can to prevent harm to people and the environment, distributing environmental harms and benefits fairly, and protecting the earth for future generations. CPR rejects the view that the economic efficiency of private markets should be the only value used to guide government action. Rather, CPR supports thoughtful government action and reform to advance the well-being of human life and the environment. Additionally, CPR believes people play a crucial role in ensuring both private and public sector decisions that result in improved protection of consumers, public health and safety, and the environment. Accordingly, CPR supports ready public access to the courts, enhanced public participation, and improved public access to information. The Center for Progressive Reform is grateful to the The John Merck Fund and the Bauman Foundation for funding this white paper. CPR also thanks the Public Welfare Foundation and the Deer Creek Foundation for their generous support of CPR's work on regulatory issues in general.

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BIOGRAPHY

Rena Steinzor

Rena Steinzor is a Professor at the University of Maryland School of Law and President of the Center for Progressive Reform (www.progressivereform.org). She teaches an environmental survey course, as well as offerings in risk assessment, critical issues in law and science, legal methods, contracts, and an introduction to the administrative system. During the course of her academic career, Professor Steinzor has written extensively on efforts to reinvent environmental regulation in the United States, the use and misuse of science in environmental policy making, and the devolution of legal and administrative authority to the states.

Professor Steinzor edited the book *A NEW PROGRESSIVE AGENDA FOR PUBLIC HEALTH AND THE ENVIRONMENT* (Carolina Academic Press 2005) with Professor Christopher Schroeder of the Duke Law School. The book proposes an alternative set of values and principles that should guide efforts to reform environmental law. She worked with Professor Wendy Wagner of the University of Texas School of Law, to edit a book of essays by prominent academics entitled *RESCUING SCIENCE FROM POLITICS* (Cambridge University Press, 2005) writing an introduction and conclusion summarizing the issues and recommendations suggested by the book. Professor Steinzor's book entitled *MOTHER EARTH AND UNCLE SAM: HOW POLLUTION AND HOLLOW GOVERNMENT HURT OUR KIDS* was published by the University of Texas Press in the fall of 2007.

Professor Steinzor is the president of the Center for Progressive Reform (CPR) (www.progressivereform.org), a think tank comprised of some 52 member scholars from universities across the United States. CPR is committed to developing and sharing knowledge and information, with the ultimate aim of preserving the fundamental value of the life and health of human beings and the natural environment. One component of CPR's mission is to circulate academic papers, studies, and other analyses that promote public policy based on the multiple social values that motivated the enactment of our nation's health, safety and environmental laws. CPR seeks to inform the public about scholarship that envisions government as an arena where members of society choose and preserve their collective values. CPR rejects the idea that government's only function is to increase the economic efficiency of private markets.

Before joining the law school faculty, Professor Steinzor was the partner in charge of the environmental practice at Spiegel & McDiarmid, a Washington D.C. Law firm specializing in the representation of state and local government entities in the energy and environmental areas. Prior to joining the firm, Professor Steinzor was counsel to the Subcommittee on Commerce, Transportation & Tourism of the House Energy & Commerce Committee, which was then chaired by James J. Florio (D-N.J.). She advised the Subcommittee during its consideration of the Superfund Amendments and Reauthorization Act of 1986 and the Asbestos Hazard Emergency Response Act of 1986. She also served as an attorney advisor to Commissioner

Patricia P. Bailey of the Federal Trade Commission and worked as a consumer protection attorney at the FTC in various staff positions.

Professor Steinzor is a 1976 graduate of Columbia Law School and a 1971 graduate of the University of Wisconsin.

Chairman BROUN. Thank you, Ms. Steinzor. Mr. Walls, you are recognized for five minutes.

**TESTIMONY OF MR. MICHAEL P. WALLS,
VICE PRESIDENT OF REGULATORY AND TECHNICAL AFFAIRS,
AMERICAN CHEMISTRY COUNCIL**

Mr. WALLS. Good afternoon, Dr. Broun, Ranking Member Bonamici, Chairman Schweikert, and the Members of the Committee. We very much appreciate the opportunity to appear here today to comment on progress in the IRIS program.

You can count me among the fans of Ken Olden. We would like to compliment Ken for his leadership in the IRIS program. The changes he has instituted since the NAS report in 2011 is—are bringing IRIS closer to a high standard of public engagement, transparency, and openness. We share his interest, and the program's interest, in assuring that IRIS assessments can help EPA and others do a better job of protecting health and the environment.

We are concerned, however, that some of the policies and practices in the program continue to perpetuate the development of unrealistic overestimates of risk. These shortcomings can have real, if unintended, consequences. And that is because the risk management decisions that are made by federal and state governments, for example, routinely draw upon the numbers generated in assessment programs like the IRIS program.

Now, ACC recently released a set of principles that set out attainable high level benchmarks for federal assessment programs. Our principles focus on four areas, improvement in assessment design, improvement in data and method integration and review, how those assessments are communicated, and review and accountability in those programs. Our principles are consistent not only with the NAS reports, but are consistent as well with the administration's own science integrity goals.

At this point in time, however, and I think as Dr. Olden has noted, much work remains to be done to ensure those benchmarks are achieved in the program. The 2011 report identified significant scientific shortcomings in the program. EPA, to its credit, is committed to fully implementing those recommendations.

But now, three years after the 2011 report was released, many of the most critical changes remain to be fully implemented. In fact, materials released by the agency just last week—in those materials released just last week, EPA indicated that only two of the chemicals now in the IRIS pipeline even have any chance of being fully consistent with the 2011 recommendations, as well as the enhancements that Dr. Olden himself has implemented. The NAS's 2014 report acknowledged that progress has been made. It also reiterated several of the same concerns noted in 2011, and made further recommendations for improvement.

Now, in our view, the most critical area for IRIS reform is evaluating and integrating scientific evidence in a transparent and robust manner. For example, IRIS has identified study quality considerations for certain scientific evidence, but the assessments have not systematically and transparently evaluated the studies against

those considerations. NAS recommended that in 2011, and did so again in 2014.

IRIS assessments needs to consistently address mode of action. That is how the human body works, and the way the chemicals interact with the body at different levels of exposure. But EPA's approach, however, has left stakeholders guessing about how mode of action and mechanistic information will be used. If IRIS assessments are designed well from the very beginning, the agency can organize the available information to evaluate the plausible alternative hypotheses, and they can do so in a much more timely way. They will be much more productive at getting assessments completed. We think EPA should also articulate a better standard for using data, instead of default assumptions, as well as more effectively addressing peer review.

Finally, how the agency characterizes and communicates this information to the public is critically important. When assumptions are used in lieu of data, the assumptions should be disclosed, along with the justification for their use. The NAS this year called on the EPA to develop guidelines for uncertainty analysis and communication. The IRIS assessments themselves should provide a complete picture of what is known and what is inferred.

But just this past Monday, at a meeting of the chemical assessment advisory committee, in their review of the ammonia assessment, it demonstrated that the panel itself couldn't figure out why EPA—how EPA chose some numbers, and why they did that. So we are looking forward to continuing our work with your Committee, with Dr. Olden, and other stakeholders to make sure that the NAS recommendations, as well as the principles we have articulated are implemented in the program.

We hope, in fact, that other EPA program offices, and other federal agencies, will carefully consider the recommendations by the NAS to make appropriate improvements in their own programs. We share a mutual interest in ensuring that high quality information is applied to make better, more timely public health decisions. Thank you.

[The prepared statement of Mr. Walls follows:]



**Written Statement of
Michael P. Walls
Vice President, Regulatory and Technical Affairs
American Chemistry Council**

**Before the
U.S. House of Representatives
Committee on Science, Space, and Technology
Subcommittee on Oversight and Subcommittee on
Environment**

**Regarding a Hearing on
“Status of Reforms to EPA’s Integrated Risk Information
System”**

July 16, 2014

I. Federal Chemical Assessment Programs Must be Scientifically Based

On behalf of the members of the American Chemistry Council (ACC),¹ I very much appreciate the opportunity to appear today to discuss an area that has important implications about the role of science in regulatory decision-making.

ACC and its member companies care deeply about how scientific information is used, evaluated, and disseminated by the Environmental Protection Agency (EPA) and other federal agencies.

Federal chemical assessments focus on understanding the inherent properties of substances in order to determine the likelihood of harm from a specific exposure. The public, businesses, and regulators at all levels of government look to these assessments as a reliable source of information about the potential hazards and risks associated with chemicals.

The outputs of federal assessments are a critical part of the decision-making process for chemical management regulatory programs (e.g., Toxic Substances Control Act) and environmental regulations (e.g., Clean Air Act). Access to accurate and useful data regarding potential hazards and risks is necessary in order for these programs to effectively protect human health and the environment, as well as provide for the development and use of chemicals that are vital to everyday life.

According to recent reports and studies, the scientific foundation underpinning these programs must be improved to ensure agencies produce timely and credible assessments.

Objective scientific analysis and transparency must be at the core of how the federal government evaluates the safety of chemicals. Flawed assessments can contribute to a lack of confidence in federal and state chemical management programs and environmental regulations, all of which routinely rely on the assessments. They can also create public confusion and unwarranted alarm and may lead to unnecessary cost, product de-selection, and litigation, which ultimately can have negative economic impacts without sound scientific basis. Moreover, these shortcomings may have further significant unwarranted economic impacts, because risk management decisions throughout the federal government, as well as state governments, routinely draw upon the risk numbers contained in the assessments.

ACC believes that the federal government must apply a more advanced scientific approach to chemical hazard and risk assessments. We have serious concerns that without additional changes, the federal government's policies and practices will continue to perpetuate the development of unrealistic overestimates of risks.

¹ The American Chemistry Council represents over 160 member companies in the \$812 billion enterprise that is American chemistry. With continued access to abundant supplies of natural gas from shale deposits, the industry's competitive edge has been substantially enhanced, and the United States is now one of the most attractive places in the world to invest in chemical manufacturing. ACC estimates that over \$117 billion will be invested in American chemistry between now and 2020, adding to the \$35 billion invested in 2013 alone. More than 96 percent of all manufactured goods are touched directly by the business of chemistry, which provides over 790,000 domestic jobs and accounts for 12 percent of U.S. exports.

ACC recently released a set of comprehensive chemical hazard and risk assessment principles² that outlines a series of attainable, high-level benchmarks for modernizing federal chemical hazard and risk assessment programs. A copy of our principles is attached to this testimony. Our principles outline four key areas for improvement: 1) the design of assessments; 2) the data and methods used in assessments, importantly including how scientific evidence is judged and integrated; 3) the communication of assessments; and 4) review and accountability. These principles are relevant to all federal chemical hazard and risk assessment programs (such as NIEHS's Report on Carcinogens, ATSDR's Toxicological Profiles, and EPA's TSCA work plan assessment program), not just the IRIS program.

II. The NAS Has Outlined a Series of Recommendations for Improvements in the IRIS Program

In 2011, the National Academy of Sciences (NAS) review of EPA's draft formaldehyde IRIS assessment included an entire chapter³ that addressed concerns about the scientific shortcomings across the IRIS program. The NAS report was, in ACC's view, a tipping point for bringing much-needed attention and oversight to the IRIS program. EPA has committed to implementing these recommendations.⁴

Three years after that report was released, however, many of the most critical changes needed to achieve the scientific standards articulated in the 2011 NAS recommendations have not been fully implemented. In fact, just last week,⁵ EPA indicated that it expects to fully implement the 2011 NAS recommendations in only two chemical assessments in the IRIS queue.

Six weeks ago, the NAS released a second report⁶ that demonstrates EPA has much work to do to ensure that the IRIS program is effective and efficient. The 2014 report reiterated many of the same concerns noted in the 2011 report and provided further recommendations for improvement, particularly in the area of systematic review. Although the 2014 report does note several areas of improvement, the unfortunate fact is that not a single IRIS assessment, either draft or final, implements all the NAS recommendations.

EPA has made important progress in addressing some of the concerns raised by the 2011 NAS report. Dr. Ken Olden has provided important leadership in driving the IRIS program to achieve a higher standard of public engagement, transparency, and openness. Dr. Olden has taken steps that, when fully implemented, will allow for substantive discussion with stakeholders even before the draft assessment is released.

For example, Dr. Olden has initiated a series of bi-monthly meetings in which EPA actively seeks input from stakeholders to address problem formulation and to discuss important scientific issues. It is our hope that these early discussions will lead to scientifically robust draft

² See <http://www.americanchemistry.com/Media/PressReleasesTranscripts/ACC-news-releases/ACC-Announces-New-Principles-to-Enhance-Chemical-Hazard-and-Risk-Assessments.html>.

³ See http://www.nap.edu/catalog.php?record_id=13142.

⁴ See <http://www.epa.gov/iris/pdfs/irisprogressreport2012.pdf>.

⁵ See [http://yosemite.epa.gov/sab/sabproduct.nsf/C50769FFFA37E22B85257D0F0057E2AB/\\$File/PDF+of+Ammonia+panel+presentation.PEROVICH.07.07.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/C50769FFFA37E22B85257D0F0057E2AB/$File/PDF+of+Ammonia+panel+presentation.PEROVICH.07.07.pdf) at slide 9.

⁶ See National Academy of Sciences, Review of EPA's Integrated Risk Information (IRIS) Process, http://www.nap.edu/catalog.php?record_id=18764.

assessments that more accurately reflect up-to-date knowledge of modes of action and hazards and risks at environmentally relevant levels of exposure.

III. IRIS Reforms Must Continue

The most critical area for IRIS reform -- evaluating and integrating scientific evidence in a transparent and robust manner -- remains to be achieved. For instance, the IRIS program has identified some study quality considerations for certain types of scientific evidence, but assessments have not systematically and transparently evaluated each of the studies against these considerations.

EPA must also develop and use pre-defined, objective criteria to evaluate the quality and relevance of all studies (animal, human, and mechanistic) in a transparent manner. The NAS recommended this in 2011 and again stressed the importance of study quality evaluations in its 2014 report. Other programs, such as EPA's High Production Volume Challenge Program and Office of Pesticides Program, as well as the Organisation for Economic Co-operation and Development, have routinely used such criteria for evaluating animal toxicity studies for many years.

Criteria have also been published in the peer reviewed scientific literature for evaluating *in vitro* studies and human epidemiological studies for quality and reliability. EPA has not articulated a rationale for not adopting and implementing these readily available approaches.

The availability of defined criteria is a critical early step to ensure that all studies are not simply treated as being of equal quality. With pre-defined, objective criteria, EPA can comprehensively review, give appropriate weight to, and integrate into its assessments data from laboratory experiments, epidemiological investigations, and cutting-edge mechanistic research from all relevant studies (including those that comport with Good Laboratory Practice [GLP] and those that do not) from all investigators, regardless of affiliation or funding source. Done correctly, this will ensure that the IRIS program gives more weight to results of the most relevant and highest quality studies than results from poorer quality and less relevant studies.

Having pre-defined criteria for including and excluding studies is a critical component of any systematic review. Although EPA has been more transparent in defining search criteria for studies to ensure key investigations are not missed, comparable progress in evaluating study quality, including internal and external validity, has not been made.

EPA's approaches to integrating evidence have left stakeholders guessing as to how mode of action, which relates to how the human body works and the way chemicals interact with the body at different levels of exposure, and mechanistic information will be used. In order to modernize IRIS assessments so that they use all available and relevant high-quality information, EPA needs to consistently address mode of action. By designing IRIS assessments from the start to fully integrate current knowledge on mode of action, the Agency can organize the available data to objectively evaluate all plausible alternative hypotheses that may be supported by the data.

For example, independent researchers supported by ACC's hexavalent chromium panel recently completed a multimillion dollar scientific research program focused on characterizing the mode of action (following EPA's guidelines) for hexavalent chromium. These research

results ensure that, in lieu of unrealistic default assumptions, solid scientific data is available for use in IRIS and other federal and state program assessments. With these data, EPA can develop a more accurate and realistic assessment of the potential risks to humans at environmental levels of exposure.

This extensive research made use of cutting-edge science from over a dozen research organizations, the insights of an external peer review panel for the research protocol and major findings, and culminated in more than a dozen scientific articles published in leading peer reviewed journals. ACC is concerned that, despite the new science with its multiple peer review steps, EPA may continue to inappropriately give greater weight to default cancer risk assessment approaches that are based on a 1970s understanding of the processes of carcinogenesis.

For example, in 2011 the NAS admonished the Agency for failing to embrace solid scientific research on biologically based dose-response (BBDR) modeling in its draft formaldehyde assessment. The NAS noted that EPA's "manipulations are extreme, may not be scientifically justified, and should not have been used as the basis of rejection of the use of the BBDR model in its assessment."

In our view, EPA's assessment of hexavalent chromium will be a critical litmus test. If EPA objectively evaluates and fully uses the mode of action data, then the Agency will signal a true commitment to implement both the NAS recommendations and its own more recent guidelines.

It would also be helpful if EPA could better articulate, in advance of conducting assessments, the standards for using data rather than assumptions and scientific information rather than defaults. To comprehensively evaluate the potential toxicity and risks of a substance, EPA should evaluate multiple alternative hypotheses to see which ones are best supported by the available data, and present central estimates, not just upper bounds, consistent with the recommendations in the 2014 NAS report.

The IRIS program has begun to draft an IRIS Handbook to provide a roadmap for implementation of the 2011 NAS recommendations. The draft Handbook is not yet complete, and as EPA has acknowledged, several pieces are missing. The missing elements include:

- Integrating evidence (epidemiological, toxicological, and mechanistic data) to identify hazards and transition to dose-response analysis;
- Conducting dose-response modeling;
- Extrapolating to lower doses and response levels;
- Considering susceptible populations and lifestyles;
- Developing candidate toxicity values;
- Characterizing confidence and uncertainty in toxicity values; and
- Selecting final toxicity values.⁷

The 2014 NAS report is silent on many of these important topics, as the Agency was not yet ready to provide drafts on these elements. The 2014 NAS panel also noted the need for peer

⁷ See EPA Jan 30, 2013, Part 1: Status of Implementation of Recommendations, http://www.epa.gov/IRIS/pdfs/IRIS%20Program%20Materials%20to%20NRC_Part%201.pdf, at page F-1.

review before making the Handbook final. ACC agrees with that suggestion. In addition, EPA needs to engage stakeholders as it works to update and complete the draft IRIS Handbook. Many pieces of the current draft Handbook, such as the development of a causality framework for non-cancer endpoints, need significant re-tooling. IRIS assessments will benefit greatly if the program engages stakeholders early in the development process.

Peer review in the IRIS program also needs to be enhanced. While the Chemical Assessment Advisory Committee (CAAC) is a helpful development, EPA also needs to ensure that this panel, or a similar independent panel, is used to review IRIS guidance. The CAAC should be engaged not only on chemical specific reviews, but also in evaluating cross-cutting scientific issues that can impact multiple assessments.

As EPA's Science Advisory Board (SAB) and Board of Scientific Counselors (BOSC) have recommended, strategies should be developed to more efficiently address peer review comments.⁸ The joint SAB and BOSC report notes the NAS example of an independent review monitor to provide critical guidance on addressing comments. Similar to the role of a journal editor, the NAS review monitor helps to ensure that comments from reviewers have been appropriately and sufficiently addressed.

Currently, the IRIS process lacks an independent review monitor. Instead, EPA staff (the authors of the draft assessments) have full discretion to determine which peer review and stakeholder comments will be the subject of a response. EPA staff also determine if the Agency's response is sufficient. Further improvements are necessary in this area and should be incorporated into the IRIS Handbook.

An important area not addressed in the draft Handbook or by the NAS is how the IRIS program prioritizes its resources and the list of chemicals that will be evaluated. Considering the efforts involved in completing an IRIS assessment, ACC believes the program should focus on those chemicals with robust scientific databases, significant uses, and potential exposures. Most importantly, the program needs to provide a clearly articulated rationale for assessing substances. Determining priorities is an area where the IRIS program could benefit from further input and dialogue with stakeholders.

Finally, how risk information is characterized and communicated to the public is critically important. When assumptions are used in lieu of data, the assumptions must be disclosed along with the justification for their use. The final characterization of hazards and risks should provide a complete picture of what is known and what has been inferred and should present results based on alternative plausible assumptions. The 2014 NAS report noted the importance of developing guidelines for uncertainty analysis and communication. The NAS also recommended improving the way EPA presents dose-response estimates, in particular calling for the presentation of two estimates, including a central estimate. Presentation of both the central estimate and upper bound should commence today and should be included in every draft and final IRIS assessment henceforth, as such calculations are readily derived. We look forward to seeing these and other recommendations implemented within the IRIS program.

⁸ See Sept 28, 2012, report, [http://yosemite.epa.gov/sab/sabproduct.nsf/3822EB089FCCB18D85257A8700800679/\\$File/EPA-SAB-12-012-unsigned.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/3822EB089FCCB18D85257A8700800679/$File/EPA-SAB-12-012-unsigned.pdf).

ACC appreciates the opportunity to comment on developments in the IRIS program. We look forward to working with EPA and Congress to ensure that federal chemical assessments meet appropriate standards for quality, reliability, and confidence.

Principles for Improving Federal Chemical Hazard and Risk Assessment Programs



Federal assessments of chemical hazards and risks are a key component to establishing a successful regulatory system. Assessments focus on understanding the inherent properties of substances in order to determine the likelihood of harm from a specific exposure. The public, businesses, and regulators at all levels of government look to these assessments as a reliable source of information about the potential hazards and risks associated with chemicals.

The determinations from assessments are a critical part of the decision-making process for chemical management regulatory programs (e.g., Toxic Substances Control Act) and environmental regulations (e.g., Clean Air Act). Access to accurate and useful data regarding potential hazards and risks is necessary in order for these programs to effectively protect human health and the environment, as well as provide for the development and use of chemicals that are vital to everyday life.

Unfortunately, too many assessments fail to consistently meet the benchmarks of objectivity, transparency, and scientific accuracy. Delays often arise as a result of the need to address shortcomings in draft assessments. Furthermore, flawed assessments may create public confusion, stir unwarranted alarm, and lead to unnecessary regulatory actions, product de-selection, and litigation. All of which only serve to further erode public confidence in chemical management programs.

Given the central role assessments have in regulatory decision making and to ensure that regulatory actions on chemical substances are based on a firm scientific foundation, the U.S. government should incorporate the following principles into chemical assessment programs:



DESIGN

1. **ENSURE KEY ISSUES ARE IDENTIFIED PRIOR TO INITIATION OF THE ASSESSMENT:** The purpose, scope, and technical approaches that will be used in assessments need to be delineated as part of the design process. Assessments should be tailored to meet the intended purpose, and stakeholders should be engaged during problem formulation. As agencies develop or revise guidance for hazard and risk assessment programs, stakeholders should have the opportunity to provide input as drafts are developed. Draft guidance should be submitted for public comment and peer review.
2. **UTILIZE MODERN SCIENTIFIC INFORMATION AND TOOLS RATHER THAN CONTINUING TO RELY ON OUTDATED ASSUMPTIONS:** Reliance on defaults should be minimized. In many cases, government hazard and risk assessment programs rely on assumptions and default approaches developed in the 1970s. Today's scientists and health professionals have a wealth of knowledge including 21st-century understanding of how the human body works and the way chemicals interact with the body and the environment at different levels of exposure. This modern-day knowledge must be applied when determining chemical safety.



DATA & METHODS

3. **INTEGRATE STUDIES TO ASSESS THE OVERALL WEIGHT OF THE EVIDENCE:** Assessments must rely on the best available scientific information, and they must employ consistent, objective methods and models to derive realistic determinations of hazards and risks at environmentally relevant levels of exposure. Scientifically valid, up-to-date data and knowledge of possible hazards and risks of substances should be used. All assessments must be based on a framework that takes into account - and integrates - all relevant studies, while giving the greatest weight to information from the most relevant and highest quality studies.
4. **DEVELOP AND APPLY CONSISTENT CRITERIA FOR EVALUATING DATA AND FOR SELECTING STUDIES USED IN ASSESSMENTS:** Transparent criteria must be established upfront and then consistently applied throughout the assessment to identify studies and to evaluate their quality, relevance, and reliability.



COMMUNICATION

5. **ENSURE ASSESSMENTS ARE TRANSPARENT:** Agencies must disclose key information used to develop assessments. When assumptions are used in lieu of data, the assumptions must be disclosed along with the justification for their use. The impact of each assumption on the evaluation should be clearly stated. Publicly available electronic dockets should be used to capture all materials, including supporting documentation, as assessments go through the development and public comment process.
6. **CHARACTERIZE HAZARDS AND RISKS FULLY AND ACCURATELY:** Hazards and risks must be objectively characterized and presented in a manner understandable to stakeholders and risk managers. The characterization should provide a full picture of what is known and what has been inferred and should also present results based on alternative plausible assumptions. When a screening level assessment indicates potential concern, prior to initiating additional risk management actions, a refined assessment should be conducted to more accurately determine hazards or risks. When going beyond screening level, assessments should include central estimates and ranges; it is not sufficient to rely on theoretical maximum exposure estimates to characterize potential risks.



REVIEW & ACCOUNTABILITY

7. **ENHANCE SCIENTIFIC PEER REVIEW AND RESPONSIVENESS:** Assessments must be subject to appropriate review by independent experts based on the importance and complexity of the decision. Peer reviewers must be fully independent from the program issuing the assessment. Peer review panels should be assembled in accordance with appropriate policies to ensure the range of technical expertise required is achieved, perspectives are balanced, and potential financial conflicts of interest are rigorously and fairly evaluated.
8. **IMPROVE ACCOUNTABILITY:** Processes need to be in place to ensure that public comments and peer review findings and recommendations are completely addressed and that legitimate scientific concerns are not disregarded. An independent accountability procedure should be implemented to verify that revised assessments are accurate, that they are fully responsive to comments and peer review recommendations, and that the necessary scientific and process improvements are embodied in specific chemical assessments.

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Chairman BROUN. Thank you, Mr. Walls. We have been informed that we are going to start having votes at about 2:10, about a minute or a minute and a half from now, and it is going to be long series. So, to try to expedite things, and get to as many Members as we possibly can, the minority and I have agreed that we are going to limit each Member to three minutes so that we can try to get through as many Members as possible. We will offer you all the opportunity to answer questions, and their questions for the record, QFRs, as we normally call them, so please be expeditious in giving those back to us. Thank you all for your testimony. I will open the first round of questions now, and I recognize myself for three minutes.

Dr. Olden, as I mentioned in my statement, I appreciate all of your efforts to reform the IRIS program, including your attempts to increase transparency and stakeholder input. I do wonder, however, when will this process be completed, and when will the EPA publish its first IRIS assessment that will reflect all of the recommendations and suggestions offered by NRC to substantially improve the program?

And then, furthermore, do you anticipate the first couple of IRIS assessments that will incorporate all of the NRC recommendations to be on new chemicals, and if so, which ones will be first, or will there be updates of old assessments, and if so, which ones?

Dr. OLDEN. Chairman Broun, any chemical that was started after the 2011 formaldehyde report will have all the recommendations that were included in the formaldehyde NRC committee report. So how many chemicals that is, I am not absolutely certain. But I would say by—in three to five years we will have completely implemented all the recommendations of the NRC reports.

Chairman BROUN. Are you talking about three to five years from now, or when you began the process?

Dr. OLDEN. —three to five years from now.

Chairman BROUN. Okay.

Dr. OLDEN. Right.

Chairman BROUN. Are new chemicals involved in the assessment, or are you just going to do old ones? And which ones are you going to test?

Dr. OLDEN. There are new chemicals in the pipeline that will be involved in the assessment. And there are probably some old ones. I can get back to you with the specifics. But there will be both new, and possibly some old chemicals.

Chairman BROUN. Okay.

Chairman BROUN. Can you give us a number?

Dr. OLDEN. What we are doing now is doing a strategic—long term strategic planning to identify the needs of the agency. And once we get—so we send a survey out to all the program directors and regional directors, and we are getting that information back. When we assemble that information, we will make—know which chemicals the agency needs, and we will make assessment of those chemicals our highest priority.

Chairman BROUN. Thank you, Dr. Olden. Ms. Bonamici, you are recognized for three minutes.

Ms. BONAMICI. Thank you very much, Mr. Chairman.

Ms. Steinzor, you mentioned in your testimony some of the health effects of chemicals for which IRIS has provided scientific documentation, for example—or scientific determinations, excuse me, brain damage, cardiovascular illness, reproductive dysfunction, cancer. That is a list that should cause us to pay attention, and I want to bring up something that you mentioned in your written testimony, the January 2014 chemical spill in West Virginia. As you indicated in your testimony at the time of the spill, the chemical being used, called Crude MCHM, was not in the IRIS database.

So, briefly, and then I will ask you to expand in writing, under the current IRIS and EPA process, what would have to happen before a chemical like MCHM would be subject to an IRIS assessment?

Ms. STEINZOR. Well, the problem with that chemical is it is not listed in any of the statutes, such as the Clean Air Act or the Safe Drinking Water Act, as being a contaminant of concern, and yet we saw that it caused very grave problems in West Virginia. For it to make its way onto the IRIS list, and actually have an assessment completed, our calculations are it would take decades at the rate they are going, and that is very unfortunate.

As you know, the people there have been told that they need to make a personal decision about whether to shower, or bathe their babies in the water.

Ms. BONAMICI. And I am going to try to get a couple more questions in. Now, recently this Committee took up a bill alleging secret science at the EPA. We hear a lot about the need for transparency. Now, it is my understanding that the companies do not have to demonstrate the safety of their products. And, in fact, safety data is often treated as proprietary. So we all know that we need chemicals for modern society, but how can we be confident that the chemicals in the marketplace are not harming us?

Ms. STEINZOR. I don't think we can be confident, as the West Virginia example shows, and I would urge you to take a very careful look at that bill. That bill would make it even more difficult for EPA to assess chemicals by raising the burden of what kind of evidence they have to have, in lieu of a testing requirement, very high.

Mr. WALLS. Ms. Bonamici, may I make a comment quickly on that?

Ms. BONAMICI. Well, I only have 41 seconds. For the record, please do submit.

Dr. Dorman, thank you for the Academy—for all your work that you have done. Can you tell me when the Academy's work will be completed, and at what point will you be finished with changing the process, or contributing to the process?

Dr. DORMAN. So with respect to the report that was issued in May, I mean, that is a project that has been completed. One of the things to keep in mind is that the Academy's activities, having been a member of several committees now, have largely been directed by either Congress, mandated by Congress, or else requested by EPA. And so, really, a lot of the work that the Academies is doing with respect to the IRIS program is being driven by those factors.

Ms. BONAMICI. And do you still have productive contributions to make?

Dr. DORMAN. So right now to my knowledge, the Academies—the only IRIS process—one that we are looking at right now, or the Academies is looking at, is related to arsenic.

Ms. BONAMICI. Thank you. I am out of time, and, Dr. Olden, I will be submitting more questions for the record. I yield back—

Chairman BROUN. Thank you, Ms. Bonamici.

Chairman Schweikert, you are recognized for three minutes.

Mr. SCHWEIKERT. Thank you, Mr. Chairman. It feels sort of like the lightning round. As Ms. Bonamici touched on, one of the benefits, obviously, of the Secret Science Bill is if EPA uses industry data, it has to become public. The baseline data sets become public. So I am hoping that actually sort of provides a benefit for everyone.

Mr. Dorman, I have one concern, and let us see if I can articulate this quickly. A standard parts per million is created in this process. Don't we have OSHA, CDC, even other parts of EPA, and then on occasion I will see European standards, as well as others. Are we in a world right now where we have lots and lots of different benchmarks being offered? Is there a need to start trying to do a consolidation of what is the standard of health attributes? And then—first that one, then there is an auxiliary to that.

Dr. DORMAN. So you raise a great point. There are a number of different agencies charged by individual companies, or countries, to try to come up with different types of exposure standards, for example, Health Canada versus EPA, and sometimes there are divergent numbers that are developed both within the United States and elsewhere. A lot of that depends upon what the populations at risk sometimes represent. So, for example, if OSHA is creating a standard for workers, that standard may be very different than what EPA is required to do for the general population.

But the methodologies—I think one of the things that our committee was stressing is that in any case, what EPA—when they are developing those numbers, try to be as transparent as possible so people can look at how those numbers were actually developed.

Mr. SCHWEIKERT. Okay. Mr. Dorman, so, if we knew all these different regulators that are publishing data on different chemicals are following a standardized methodology for analysis—

Dr. DORMAN. Right.

Mr. SCHWEIKERT.—, then there is the next part of that. Instead of saying, here is my benchmark, it is blank parts per million, shouldn't it be blank parts per million when handled in this fashion? In this fashion, you might have other types of mitigation. Are we also doing a good enough job providing those other levels a definition of it also has to do with environment, being used in industry, mechanics, the other attributes around it?

Dr. DORMAN. Right. So, very quickly, again, it comes back to—for example, on the OSHA numbers, those oftentimes will look at personal protection, which was—not be available to the general population, which EPA is now viewing for, say, the RFC or RFD values. So these numbers that EPA is developing are for unprotected populations at risk.

Mr. SCHWEIKERT. Okay. And, Mr. Chairman, I promise all of you I will have some questions in writing. I have a sort of a fixation

on data, whether you think it helps you or hurts you, becoming public, because I think we need to also trust the kids at a university, a left wing group, a right wing group, from being able to have opportunities to analyze data, and compare with other data sets. With that, I yield back, Mr. Chairman.

Chairman BROWN. Thank you, Mr. Schweikert. Ms. Clark, you are recognized for three minutes.

Ms. CLARK. Thank you, Mr. Chairman.

Dr. Dorman, when Dr. Samet testified before this Committee on the 2011 formaldehyde report, he made it very clear that the NAS panel was not calling for the EPA to suspend IRIS assessments, and was not saying that they could not do quality, solid assessments. Instead, was recommending reforms in the process that could be implemented in parallel with continuing IRIS assessments. Can you tell me, is that still the position of the NAS panel?

Dr. DORMAN. So I think that Dr. Samet's comments were echoed in our recent IRIS report, and—

Ms. CLARK. Um-hum.

Dr. DORMAN. —the bottom line is that for EPA, when the Committee was trying to look at the changes that EPA was making, those were in progress. And so what we felt as a committee, and felt strongly, was that implementation of different attributes within the process may take different periods of time in order to fully implement. And so we recognize that, both in the formaldehyde report that I served on, as well as the IRIS committee.

And so I think the bottom line was neither committee had the anticipation that we would see full cloth changes, but rather we were seeing a progress that was occurring, that we could then judge to see where they were going.

Ms. CLARK. And in both the new report, and in your testimony, it was found there were substantial improvement in EPA's process, in line with those recommendations from 2011. Do you see any evidence that EPA is producing what some have called flawed assessments?

Dr. DORMAN. So I think it is important that we were charged with looking at the process, rather than any individual assessments, per se. So we weren't asked to do any independent assessments, or reviews of assessments, but what we did see was a pattern on the part of EPA in which they were very proactively implementing the changes in the formaldehyde. And what we see is, once these are all fully implemented, we believe that the quality of the assessments will actually improve dramatically.

Ms. CLARK. Thank you.

Mr. Walls, in your testimony you talked—referred a few times to timely manner of these assessments. Do you believe the IRIS program is completing assessments in a timely manner?

Mr. WALLS. Congresswoman Clark, I think our view would be that IRIS can do a better job, and, if it systemically implements the recommendations made by the NAS, for example, can get to a steady state stage, where they can regularly and confidently produce these assessments.

Ms. CLARK. Would the industry support additional resources to make this happen for IRIS?

Mr. WALLS. We have made clear our support for the agency having appropriate resources to do this work.

Ms. CLARK. Thank you.

Chairman BROWN. Thank you, Ms. Clark.

Mr. Swalwell, you are recognized for three minutes. And please be quick, because I would like to get to Ms. Edwards, if we can, before—and give her a chance too. So you are recognized for—

Mr. SWALWELL. I will, and I have just one question for Professor Steinzor, and I am a former University of Maryland School of Law student, so I am thrilled—

Ms. STEINZOR. Fantastic.

Mr. SWALWELL. —you are there. Professor Steinzor, you acknowledged in your testimony that the science of risk is always evolving, yet the Academies have suggested, in their recent report, that EPA adopt firm stopping rules for key points in the IRIS process. Although it may appear obvious to most, could you elaborate on the need for EPA to incorporate stopping rules into the IRIS process, and how would a lack of stopping rules impact the IRIS process?

Ms. STEINZOR. So a stopping rule would be, we are going to look at this information that is available as of this point. We are going to apply a weight of the evidence analysis to it. We are going to write an IRIS profile, and then we are going to put the profile out. And if there are subsequent studies, we will take a look at those, and revise the profile as appropriate, on a cycle of five years, as an example, which is what applies to national ambient air quality standards, and it has worked fairly well.

Mr. SWALWELL. Thank you. Go Terps, and I yield back the balance of my time.

Ms. STEINZOR. Fear the Turtle.

Dr. OLDEN. May I add to that? We have, in fact, developed firm stopping rules in our enhancements that we rolled out about last summer, in July. There are firm stopping rules today.

Thank you.

Chairman BROWN. Very good. Thank you, Dr. Olden. Ms. Edwards, you are recognized for a very quick three minutes, please, ma'am.

Ms. EDWARDS. Thank you very much, Mr. Chairman, and I will be quick. My question is for Mr. Walls. You represent the American Chemical Council. Is it true that the council spent about \$2.9 million in lobbying expenses over this last year, in 2014?

Mr. WALLS. I would assume that is correct.

Ms. EDWARDS. And then in 2013 you spent about \$13 million in lobbying expenses?

Mr. WALLS. I don't have those figures in front of me, but we do make lobbying expenditures, yes, ma'am.

Ms. EDWARDS. And I just want to be clear. So my understanding is that the council has opposed the assessment for formaldehyde, opposed the assessment coming forward for arsenic, opposed the assessment coming forward for trichloroethylene, TCE, that is present in our drinking water. Is there an assessment that you all support the EPA moving forward on?

Mr. WALLS. Congresswoman, our interest is ensure that the best, highest quality, most reliable science is brought forward to make those decisions.

Ms. EDWARDS. Right. What is the——

Mr. WALLS. The regulatory——

Ms. EDWARDS. —last assessment that you—what is the last assessment that you supported the EPA moving forward on?

Mr. WALLS. We——

Ms. EDWARDS. Give me one.

Mr. WALLS. We give—we support a number of assessments. There is—EPA, for example, has a work plan chemical assessment program in the Office of Pollution Prevention and Toxics, and we have been clear that we support the agency's moving forward.

Ms. EDWARDS. Have you supported the agency moving forward on the arsenic assessment?

Mr. WALLS. Congresswoman, we have made clear that our interest is in——

Ms. EDWARDS. Have you supported the EPA moving forward——

Mr. WALLS. To date——

Ms. EDWARDS. —on the arsenic assessment?

Mr. WALLS. We support moving forward on assessments in a way that is——

Ms. EDWARDS. Have you supported the EPA moving forward on the arsenic assessment?

Mr. WALLS. I——

Ms. EDWARDS. Have you supported the EPA moving forward on the formaldehyde assessment?

Mr. WALLS. We have supported the agency moving forward on IRIS assessments, but to do so in a manner that——

Ms. EDWARDS. Have you—I just want a yes or no, if you could. Have you supported the——

Mr. WALLS. I can't——

Ms. EDWARDS. —EPA moving——

Mr. WALLS. I can't——

Ms. EDWARDS. —forward on the——

Mr. WALLS. —a yes or no——

Ms. EDWARDS. —formaldehyde assessment?

Mr. WALLS. —Congresswoman.

Ms. EDWARDS. No?

Mr. WALLS. We have supported moving forward on the assessment in a way——

Ms. EDWARDS. On the formaldehyde assessment?

Mr. WALLS. In a way that——

Ms. EDWARDS. Support——

Mr. WALLS. —reflects the——

Ms. EDWARDS. —the EPA——

Mr. WALLS. —recommendations made——

Ms. EDWARDS. —moving forward on the——

Mr. WALLS. —by the——

Ms. EDWARDS. —formaldehyde assessment? Did you—did the American Chemistry Council have anything at all to do, or spend any lobbying expenses, on ensuring that the EPA could not move forward, and this Congress could not move forward, on the arsenic assessment? Did you all lobby on that issue at all——

Mr. WALLS. I——

Ms. EDWARDS. —in the Congress?

Mr. WALLS. I don't have direct knowledge of that, but I assume we did, yes.

Ms. EDWARDS. I will be following up with additional questions.

Mr. WALLS. I will look forward——

Ms. EDWARDS. Thank you very——

Mr. WALLS. —to your questions.

Ms. EDWARDS. —much to the witnesses.

Chairman BROWN. Thank you, Ms. Edwards. Apologize for the fast round of questions. We have two more minutes in this vote, so we are going to submit questions for the record, and you can answer them. You can put a lot more flesh on these. Thank you for your flexibility. And, again, I apologize for the hasty period of time. I thank Members for you all's flexibility. The record will remain open for two weeks for additional comments and written questions from Members. The witnesses are now excused. This hearing is adjourned, and thank you all.

[Whereupon, at 2:27 p.m., the Subcommittees were adjourned.]

Appendix I

ANSWERS TO POST-HEARING QUESTIONS

ANSWERS TO POST-HEARING QUESTIONS

Responses by Dr. David Dorman

Dr. David Dorman

Member, Committee to Review EPA's IRIS Process, National Research Council

**Responses to Questions for the Record from Chairman Broun and Chairman
Schweikert**

"Status of Reforms to EPA's Integrated Risk Information System"

1. The NAS report appears complimentary of EPA's "trajectory" and plans. However, it is not clear which of the EPA documents reviewed by the panel have fully implemented the National Academies' 2011 recommendations or followed the approach NAS supports. Could you please provide the Committee with some examples?

Response: The NRC IRIS committee evaluated several IRIS assessments that were provided by EPA or were publically available, such as EPA's Toxicological Review of Ammonia, Toxicological Review of Methanol (Noncancer), and Toxicological Review of Trimethylbenzenes. The IRIS committee considered each assessment, particularly EPA's documentation of its implementation of the 2011 NRC recommendations that was provided as an appendix to each IRIS assessment. The committee found that implementation of the recommendations from the NRC formaldehyde report was still in process, and none of the reviewed IRIS assessments had fully implemented the 2011 NRC recommendations. However, each of the reviewed IRIS assessments included multiple elements that were consistent with the recommendations from the 2011 NRC formaldehyde report.

2. In 2011, the NAS recommended that EPA provide clear guidance guidelines for study selection. In a true systematic review, one must develop criteria in advance, and use these criteria to evaluate study quality. Is this the correct approach?

Response: It is appropriate for criteria to be established to evaluate study quality and risk of bias. That approach is consistent with the methods used by the Cochrane Collaboration and other organizations. Many different assessment tools are available, and, in some cases, tools can be developed for a specific review. As noted by the NRC IRIS committee, it is appropriate for the IRIS program to define the criteria and tools to be used to assess risk of bias as part of the protocol development process (see page 37 of the NRC report), which is defined in advance of the assessment. However, the IRIS committee recognized that assessment tools for risk of bias should be based on empirical evidence, and that information is often lacking for certain evidence streams used by the EPA IRIS program (e.g., animal and in vitro data streams).

Do the recent draft IRIS assessments that are currently undergoing review or will soon be reviewed (ammonia, trimethylbenzenes, ethylene oxide) transparently provide these criteria?

Response: A review of the EPA's Toxicological Review of Ammonia and the Toxicological Review of Trimethylbenzenes that were provided to the committee do not include a transparent description of how study quality or risk of bias would be evaluated.

Should systematic review be a priority for all draft assessments?

Response: Adoption of systematic review processes is consistent with the recommendations of the 2011 and 2014 NRC reports and is also consistent with the approaches that the IRIS program is developing. Further development of systematic review methods was viewed as a priority for the IRIS program by the 2014 NRC IRIS committee (see pages 137-138, Box 8-1).

3. What is the most significant improvement to the IRIS program, and what continues to be the most pressing challenge?

Response: The committee did not rank the improvements in any tangible way but noted that significant improvements included changes to the IRIS document structure and adoption of systematic-review principles. A pressing challenge that remains relates to EPA's development of methods for evidence integration using a qualitative structured approach or possibly quantitative approaches. Other high-priority items were identified in Box 8-1 in the 2014 NRC IRIS report.

4. Many other federal agencies – including the National Institutes of Health, OSHA, CDC, and other parts of EPA – also conduct chemical risk assessments. Could the NRC's 2014 report recommendations be applied to all federal chemical risk assessment programs, and should they?

Response: The general principles outlined in the 2014 NRC report, in particular steps up to derivation of IRIS specific toxicity values, could be broadly applied to other federal programs. Whether they should be applied represents a policy decision that is beyond the scope of the committee's work.

Further, could the recommendations in Chapter 7 of the NRC's 2011 formaldehyde report be applied to all federal chemical risk assessment programs, and should they?

Response: The general principles outlined in the 2011 NRC report could also be broadly applied to other federal programs. Whether they should be applied represents a policy decision that is beyond the scope of the committee's work.

5. To what extent does having multiple toxicity assessment sources for the same chemical present challenges for ensuring consistent risk management across the nation, and what steps has EPA taken to either minimize or explain reasons for any differences.

Response: Evaluating challenges for consistent risk management given multiple toxicity assessment sources was clearly beyond the scope of the 2014 NRC IRIS report.

6. The NRC recommends that EPA should provide technical assistance to stakeholders who don't have resources to provide input – what stakeholders did NRC have in mind?

Response: The NRC IRIS committee notes (page 23) that “even in the face of expanded transparency and enhanced stakeholder engagement, there is concern about the uneven participation of the first two principal stakeholder groups.” Earlier in the NRC report (page 21) these first two stakeholder groups were broadly identified as nongovernment organizations, such as environmental advocacy groups, and the second as industrial and government entities that produce, use, and release chemicals. The committee observed that most comments submitted to the IRIS program were provided by organizations and individuals associated with the chemical industry (page 23), suggesting the need for technical assistance to nongovernment organizations, including environmental advocacy groups.

7. At the Committee's request, the EPA Inspector General issued a report last year on the use of the IRIS database by EPA program officers and regions. According to the IG's report, approximately “one-third (34 percent) of the survey respondents reported that they have used an alternative source for toxicity values when an IRIS value was available. The primary reason selected for using an alternative source was that the alternative source was more up to date with current scientific practice or information.” Was the NRC panel aware of this report when it came out last year and did it factor into the panel's discussions as it determined that IRIS was substantially improving?

Response: The committee members were made aware of both the IG report and a GAO report that was critical of EPA (as summarized in Risk Policy Report - 06/11/2013 with links to the original reports). The IG report provided additional information regarding the need for increased efficiency in the IRIS process, which was discussed on pages 24-25 in the 2014 NRC IRIS report.

8. The NRC recently completed its review of the National Toxicology Program's (NTP) listing of formaldehyde in the 12th Report on Carcinogens. In its report, the panel concurred with the NTP's listing of formaldehyde as “known to be a human carcinogen,” and it also found “clear and convincing” evidence of “an association between formaldehyde exposure and myeloid leukemia.” This is a very different conclusion than the one found by the NRC panel in 2011 which did not find a causal link between formaldehyde exposure and leukemia. Please explain the discrepancy between the two reports, and which report should Congress view as the authoritative one on formaldehyde?

*Response: This topic was beyond the scope of the 2014 NRC IRIS report. However, on the basis of my experience as a member of the 2011 NRC formaldehyde committee and as a peer reviewer of the NRC report entitled "Review of the Formaldehyde Assessment in the National Toxicology Program 12th Report on Carcinogen," part of the discrepancy can be explained by the statements of task and approaches of the two committees. The 2014 formaldehyde committee that reviewed the NTP's assessment was asked to independently apply the NTP's listing criteria and make an "independent listing recommendation for formaldehyde and provide scientific justification for its recommendation". In contrast, the 2011 formaldehyde committee was not asked to conduct an independent risk assessment. Per its statement of task, the 2011 formaldehyde committee was asked to "comment on the cancer weight-of-evidence narrative in the draft, developed according to EPA's 2005 Guidelines for Carcinogen Risk Assessment and answer the question, is the weight-of-evidence narrative scientifically supported?" Thus, the 2011 formaldehyde committee did **not** make an independent assessment of whether a causal association existed between formaldehyde exposure and leukemia. It evaluated the evidence and methods used by EPA and concluded that EPA's conclusion of causality was not supported by EPA's narrative provided in the draft formaldehyde assessment. That conclusion was based in part by the lack of a clear framework for causal determinations. Moreover, the two programs (IRIS and NTP) use different criteria and guidelines for listing a chemical as a possible carcinogen.*

Responses by Dr. Dr. Kenneth Olden

**HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON OVERSIGHT
&
SUBCOMMITTEE ON ENVIRONMENT**

Hearing Entitled
Status of Reforms to EPA's Integrated Risk Information System
July 16, 2014

QUESTIONS FOR THE RECORD

Dr. Kenneth Olden
Director, National Center for Environmental Assessment
U.S. Environmental Protection Agency

Questions submitted by Chairman Broun and Chairman Schweikert

1. In 2011, the NAS recommended that EPA provide clear guidelines for study selection. In a true systematic review, one must develop criteria in advance, and use these criteria to evaluate study quality. Is this the correct approach? Do you believe the recent draft IRIS assessments that are currently undergoing review or will soon be reviewed (ammonia, trimethylbenzenes, ethylene oxide) transparently provide these criteria? Should systematic review be a priority for all draft assessments?

Answer: EPA agrees with and is implementing the 2011 National Research Council (NRC) recommendations regarding systematic review. Consistent with the advice of the NRC in their "Roadmap to Revision" in Chapter 7 of the 2011 NRC formaldehyde review report, EPA is implementing the recommendations using a phased approach. Specifically, NRC stated that "the committee recognizes that the changes suggested would involve a multiyear process and extensive effort..." In implementing the recommendations in a phased approach, EPA has stated that the most extensive changes are being made to documents that are in earlier steps of the assessment development process. For assessments that are in the later stages of development, such as ethylene oxide, EPA is implementing some of the recommendations without taking the assessments backwards to earlier steps in the process.

In May 2014, the NRC released their report reviewing the IRIS assessment development process. In this report, the NRC commends EPA's efforts to improve IRIS and found that the program has moved forward steadily in planning for and implementing changes in each element of the assessment process. The report also noted that EPA has made substantial improvements to the IRIS Program in a short time. The report noted that, "overall, the changes that EPA has proposed and implemented to various degrees constitute substantial improvement in the IRIS process" and that "if current trajectories are maintained, inconsistencies identified in the present report are addressed, and objectives still to be implemented are successfully completed, the IRIS process will become much more effective and efficient in achieving the program's basic goal of

developing assessments that provide an evidence-based foundation for ensuring that chemical hazards are assessed and managed optimally.” Of note, the committees agreed that the new document structure for IRIS assessments improves the organization of and streamlines the assessments, and the evidence tables and graphic displays of study findings increases clarity and transparency. These changes have been implemented in the draft ammonia and trimethylbenzenes assessments. The report stated that this approach brings IRIS assessments more in line with the state of practice for systematic reviews.

Additionally, we are actively working to develop, where necessary, and implement methodologies for the application of systematic review to all IRIS assessments. This topic will be discussed at the upcoming October 15-16, 2014 NRC Recommendations Workshop (http://www.epa.gov/iris/irisworkshops/NRC_workshop/index.htm). The workshop will include focused discussions with scientific experts on refining systematic review methodologies, as well as the systematic integration of evidence streams.

2. What is the most significant improvement to the IRIS program, and what continues to be the most pressing challenge?

Answer: Strengthening and streamlining the IRIS Program is an ongoing priority for EPA. On July 31, 2013, EPA announced a series of enhancements to help meet the goal of producing high quality scientific IRIS assessments in a timely and transparent manner. These enhancements focused on: 1) improving the scientific integrity of assessments; 2) improving the productivity of the program; and 3) increasing transparency so controversial or complex science issues are identified and debated early in the process. These changes are consistent with recent recommendations provided by the National Research Council.

The most significant improvement to the IRIS program is increased early engagement with the public to ensure that EPA identifies and addresses any controversial scientific issues earlier in the assessment development process. This early scientific engagement is anticipated to strengthen the overall quality of IRIS assessments. The most significant challenge facing the IRIS Program is meeting the needs of the agency in a timely manner. It is anticipated that enhanced stakeholder and public engagement will play a crucial role in ensuring transparency and the use of the best available science throughout the IRIS assessment process. As a result, the IRIS Program will be able to complete assessments in a timelier manner in the future.

3. In 2013, GAO reported that EPA's most recent evaluation of demand for IRIS assessments was a decade old. EPA had no plans to perform another evaluation, but recognized that due to changing conditions over the last 10 years, the 2003 evaluation was not applicable to current conditions.

- a. What progress has EPA made in identifying and evaluating demand for IRIS toxicity assessments, and what report or study, if any, has EPA produced on current demand?**

Answer: In June 2014, the IRIS Program began an agency-wide effort to determine program and regional office needs for current and future assessments (including the type of IRIS product

needed). The results of this survey will inform the next multi-year IRIS workplan. The IRIS workplan will enable the program to achieve a consistent and sustainable workflow that produces high-quality chemical assessments that are timely and responsive to agency needs. The IRIS Program anticipates making the new multi-year workplan publicly available as early as Fall 2014.

- b. Given EPA's challenges in completing enough IRIS toxicity assessments to meet their annual goals (e.g., EPA completed 4 IRIS toxicity assessments in fiscal year 2012, falling short of its goal of completing 40 assessments for that year), how has EPA considered its current resource constraints when identifying how it will meet demand?**

Answer: As noted above, EPA is conducting an evaluation of program and regional office needs for current and future IRIS assessments. Resource constraints will be considered as we develop the multi-year workplan and schedule for upcoming assessments from that survey. The survey of needs and the associated resource-loaded workplan provide agency planners with the information they need to ensure that appropriate resources are placed against the highest priority need.

EPA expects to complete more high quality IRIS assessments per year as a result of the July 2013, IRIS enhancements. Numerous assessments are at various stages of development, including public opportunities for discussion of chemical-specific assessment plans, literature searches and evidence tables, and draft assessments. In practice EPA expects that each assessment will take a shorter period of time to complete as significant science issues are better understood and are resolved earlier in the assessment development process.

4. According to data on EPA's website, 90% of the 560 completed IRIS assessments are more than 10 years old and 75% are more than 20 years old. However, over those intervening years, new data on many of these chemicals may have emerged, and certainly the methods for assessment have changed over these years (for example, as identified in EPA's 2005 Cancer guidelines). In 2009, EPA instituted a project to update older assessments, and the manager of that program (Dr. Chon Shoaf) was quoted as saying that the program would need to do 300 updates each decade just to keep from falling further behind. Has this program continued? In addition, organizations are urging the IRIS program to undertake assessments of yet additional chemicals not already on the list. What is the size of the current IRIS workload, and how do you propose to address it?

Answer: The IRIS Program has primarily focused on improving the assessment development process associated with its health assessments. These improvements have been geared towards addressing the NRC recommendations in 2011. As the focus has been on making substantial improvements to the process, the IRIS Program is only now beginning discussions on how to update older assessments. As these discussions continue, EPA will evaluate the potential options within the context of other agency needs identified by the multi-year workplan and other resource constraints. Since the July 2013 enhancements, the program has been actively

working on 21 assessments. This number includes 3 completed assessments (methanol (noncancer), biphenyl, 1,4-dioxane) and 18 that have gone to a public step as part of the IRIS Process. Additional assessments will be added over time to the existing workload in accordance with agency needs and in consideration of IRIS Program resources. The multi-year workplan will be instrumental in identifying priorities and scheduling assessments.

5. At the Committee's request, the EPA Inspector General issued a report last year on the use of the IRIS database by EPA program offices and regions. According to the IG's report, approximately "one-third (34 percent) of the survey respondents reported that they have used an alternate source for toxicity values when an IRIS value was available. The primary reason selected for using an alternate source was that the alternate source was more up-to-date with current scientific practice or information." Does it concern you that some of your colleagues at EPA don't use IRIS values and what will it take to fix this internal disconnect?

Answer: In the Office of Inspector General's report, 85 and 81 percent of respondents indicated that they used IRIS as their primary source of cancer and noncancer values, respectively. The IRIS Program believes this indicates that the values developed in IRIS assessments are of general utility to our program office and regional stakeholders. Thirty-four percent of the respondents indicated that they had experienced "a situation" in which they used an alternate source of toxicity values when an IRIS value was available; the primary reason for the use of an alternative source was because a more up-to-date value was available (68%). The agency is aware of the use of alternate sources of toxicity information and we believe that efforts to establish a multi-year workplan, as well as discussions to identify assessments that may have newer information, will ultimately reduce the frequency with which a program would feel the need to select a cancer or noncancer value from an alternative source of toxicity values.

6. In light of GAO's listing of IRIS on the "High Risk" list and the acknowledgement by EPA that it needs to both reform the program and produce/update more assessments, why did the President propose to reduce funding for the program in FY2015?

Answer: The agency is committed to effectively implementing its mission to protect public health and the environment, which depends on credible and timely assessments of the risks posed by chemicals. As such, we are committed to focusing resources on ensuring that the IRIS Program produces high quality assessments in a timely and transparent manner. Likewise, we are committed to continuing the development of high profile assessments of public health critical chemicals (such as inorganic arsenic, formaldehyde, hexavalent chromium, polychlorinated biphenyls, and ethylene oxide). The \$1.5M FY2015 budget reduction will affect primarily the development and timing of new assessments. It will not impact the development of the public health critical chemicals, which will be protected from budgetary impacts. The IRIS Program is also currently evaluating the chemical assessment demands across the Agency to address GAO's recommendations related to fully documenting the capacity needed to meet demands.

7. What is the projected cost of a typical IRIS assessment?

Answer: The resources required to complete IRIS assessments vary due to the size and complexity of the database underlying the toxicity of a given chemical. The cost of an IRIS assessment ranges from \$400,000 to \$2,500,000 in extramural funds and four to fifteen FTE's.

8. A common criticism of IRIS assessments is the tendency to be "public health protective," which can lead to unrealistically conservative assessments, which, in turn, can lead to overstated environmental risks and bad regulation. We have heard the oft-repeated mantra that IRIS assessments are purely scientific and not regulatory, but doesn't a bad risk assessment restrict a risk manager's options, ultimately forcing him or her to make a bad risk management decision?

Answer: IRIS assessments are intended to accurately and impartially reflect the science that details a chemical's toxicity. When critical information is lacking, IRIS assessments use approaches that help risk managers make decisions that are consistent with the agency's mission to protect human health and the environment. Ultimately, in the absence of data, the use of uncertainty factors and other "default" approaches is a valuable strategy to protect human health, including sensitive populations.

All the information included in an IRIS assessment, including the selection of modeling approaches and uncertainty factors, is reviewed by the Science Advisory Board (SAB) Chemical Assessment Advisory Committee (CAAC). A significant benefit of the SAB-CAAC is its independent review of the decisions made during development of the draft assessment.

A strong, scientifically rigorous IRIS Program is of critical importance and we are ensuring that IRIS assessments transparently and accurately address scientific issues and uncertainties, including the presentation of alternative analyses (e.g. modeling approaches) where appropriate. Presentation of alternative approaches in the supplemental information of an IRIS assessment informs risk managers and facilitates decision-making.

9. In 2009, you were part of a Bipartisan Policy Center report that unanimously recommended that "studies used in the formulation of regulation should be subject to data access requirements... regardless of who funded the study." Do you still agree with this statement? And how has this recommendation been implemented in the IRIS and National Ambient Air Quality Standard-setting process in your office?

Answer: Yes. This question addresses two important issues relevant to the development of IRIS assessments as well as the Integrated Science Assessments (ISA) that inform the development of the National Ambient Air Quality Standards: data access and funding source.

Transparency and scientific integrity are very important to the agency's work. Transparency is a critical element in EPA's Scientific Integrity Policy, which states, "To enhance transparency with the agency, this policy...facilitates the free flow of scientific information. The agency will continue to expand and promote access to scientific information by making it available online in open formats in a timely manner, including access to data and non-proprietary models underlying agency policy decisions." Both IRIS assessments and ISAs make information available about the

studies that inform the development of the documents through the Health Effects Research Online (HERO) database. Here, the general public can see information on the studies used in an assessment, primarily journal articles and technical reports, while adhering to distribution limitations due to copyright. Additionally, modeling code and output used in the development of an assessment is made available so that the public can see how decisions were made. The agency is currently exploring ways to make more of the underlying data available, acknowledging that in many cases, journal articles do not include the raw data supporting published results. In other cases, with human data, additional steps are essential to maintain the privacy of the personal health information of individuals who have participated in these studies.

With respect to funding source, all relevant, well-conducted, and peer-reviewed studies, regardless of funding source, and regardless of whether the results are positive or negative, are considered in the development of both IRIS assessments and the ISAs. In their 2014 review of the IRIS Process, the National Research Council (NRC) recommended that evidence evaluation and risk-of-bias analysis be conducted using methods that are "transparent, reproducible, and scientifically defensible." The NRC also recommended that funding sources be considered in systematic reviews conducted for IRIS assessments. Decisions made in IRIS assessments and ISAs continue to be based on the best available science. These topics will be discussed with systematic review experts and the public at an upcoming IRIS workshop to be held October 15-16, 2014.

10. While EPA often relies on scientific data produced by or funded by other government agencies in its assessments, those raw data are not made available to external reviewers and the public for independent evaluation. Stakeholders have tried many approaches to get these data through the Freedom of Information Act, but often come up short and if data are provided, it is not provided in a timely manner to help inform comments on the assessments. Will you ensure that all the data the IRIS program uses in its assessments are made accessible to all stakeholders (assuming appropriate privacy protections, etc...)?

Answer: EPA remains committed to transparency and scientific integrity, and the IRIS Program will continue to explore ways to increase access to the scientific information underlying its assessments. However, it is important to note that IRIS assessments typically rely on the "data" included in peer-reviewed journal articles, not the "raw data" underlying those publications and in the possession of the researcher(s). As such, the "data used in an assessment" is available in the assessment's references. In the rare cases where EPA obtains a researcher's dataset and reanalyzes the data for an IRIS assessment, the data is available when access to it is not restricted by applicable privacy requirements, confidential business claims, or similar restrictions via the IRIS website.

EPA's policy with respect to data will continue to be consistent with existing obligations to avoid disclosing material that may be confidential business information (as directed under the Trade Secrets Act and under OMB Circular A-130). In addition, the agency is committed to protecting citizens' privacy and preventing the release of personal information that could, directly or indirectly, be traced to specific individuals.

11. IRIS assessments routinely identify one or more reference values below which no bad effects in humans are expected, and these are provided to other EPA offices and other agencies as a guide for the establishment of regulations that often require control of the chemical down to the level the IRIS program has established. Several of the chemicals under the purview of the IRIS program, including methanol and formaldehyde, are produced naturally by the human body.

In the recent final assessment of methanol, your office published a reference level that, in the case of 20% of the U.S. population, is exceeded by that person's naturally-produced methanol and is also equal to the amount of methanol that is contained in just 25 ounces of orange juice.

- a. Should EPA examine these kinds of naturally-occurring chemicals differently from other chemicals, perhaps by looking more closely at the safety margins that are built into these reference values and asking whether the resulting reference values are realistic? Do you have a plan to do so?

Answer: EPA is planning to convene a scientific workshop to discuss issues related to assessing the human health risks of exposure to environmental chemicals that are also produced in the body through normal biological processes (known as "endogenous chemicals"). IRIS assessments are developed to provide information on health effects associated with exposure to chemicals from sources over which EPA has regulatory authority, including some chemicals that occur naturally, either in the environment or are endogenously produced. The assessment of health risks associated with exposure to environmental chemicals that are also produced endogenously deserves careful consideration because there are many natural products of metabolism that can have toxic effects at high enough levels. The fact that they are naturally produced does not necessarily make them "safe" at all doses. The risk evaluated for a chemical is typically the risk of an increased effect beyond the effects observed in the "unexposed" group or population. IRIS values generally already take into account amounts commonly produced by our own bodies in how they are derived.

12. Could you tell us what an "adverse effect" means to you? Does EPA have any guidance on the definition of an "adverse effect," and does the IRIS program follow this guidance?

Answer: The IRIS Program adheres to the following definition of an adverse effect: "A biochemical change, functional impairment or pathologic lesion that affects the performance of the whole organism, or reduces an organism's ability to respond to an additional environmental challenge." This definition is available online at: http://ofmpub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&vocabName=IRIS%20Glossary.

13. To what extent does having multiple toxicity assessment sources for the same chemical present challenges for ensuring consistent risk management across the nation, and what steps has EPA taken to either minimize or explain reasons for any

differences?

Answer: EPA's IRIS Program is the only federal program devoted solely to the evaluation of health hazard and dose response information for the purposes of developing cancer and noncancer chronic toxicity values for the oral and inhalation pathways of exposure for the protection of public health. In addition, the IRIS Program qualitatively evaluates cancer information to ascertain human cancer potential. EPA's program and regional offices combine information from IRIS assessments with relevant exposure information for a chemical to assess the public health risks of environmental contaminants. EPA decision-makers use these risk assessments, along with other considerations (e.g., statutory/legal requirements that can include cost-benefit information, technological feasibility, and economic factors) to inform risk management decisions. The values derived by other federal health agencies are developed in response to different mandates and for different purposes. For example, the Agency for Toxic Substances and Disease Registry (ATSDR) Minimal Risk Levels (MRLs) are developed in response to a mandate under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), to provide toxicological profiles of hazardous substances found at National Priorities List sites. According to the ATSDR website (<http://www.atsdr.cdc.gov/mrls/index.asp>), these values are intended to serve as screening levels, and are used by ATSDR health assessors to identify contaminants and potential health effects that may be of concern at hazardous waste sites. ATSDR further states that "it is important to note that MRLs are not intended to define cleanup or action levels for ATSDR or other Agencies." EPA has a Memorandum of Understanding with ATSDR, working closely on some assessments to ensure our work in developing human health assessment is complementary and to share data and information on specific assessments. Within EPA, the Office of Solid Waste and Emergency Response has outlined a hierarchy of toxicity values to be used in making decisions at Superfund sites (<http://www.epa.gov/oswer/riskassessment/pdf/hhmemo.pdf>). This directive indicates that IRIS is the preferred choice of toxicity values in Superfund risk assessment activities, and it points to other sources of toxicity values, including those developed by ATSDR and California Environmental Protection Agency, that one can use in the event that an IRIS assessment is not available for a given chemical of concern.

14. Many of the well-known pollutants of concern apparently up for assessment revision by IRIS have been previously assessed by other federal health agencies-OSHA, the National Institute for Environmental Health Sciences, ATSDR, as well as other entities like the National Academy of Sciences, the World Health Organization, or the chemical industry.

a. What is particularly essential about the IRIS Assessment updates that justify this new batch of assessments? What health benefit might be gained?

Answer: As indicated above, EPA's IRIS Program is the only federal program devoted solely to the evaluation of health hazard and dose response information for the purposes of developing cancer and noncancer chronic toxicity values for the oral and inhalation pathways of exposure. In addition, the IRIS Program qualitatively evaluates cancer information to ascertain human cancer potential. Risk management issues, such as technical feasibility or limits of detection, which are sometimes considered in the development of toxicity values by other federal agencies, are developed separately from IRIS toxicity values. IRIS assessments are the scientific foundation

for EPA decisions to protect public health, and our primary clients are the program and regional offices who nominate chemicals for addition to the IRIS agenda. IRIS assessments undergo a very rigorous review process involving the public and stakeholders at various steps in the assessment development process, as well as internal agency scientists, scientists from other federal agencies, and rigorous independent external peer review. As indicated above, the values derived by other federal health agencies (e.g., ATSDR, NIOSH, OSHA) are developed in response to different mandates and for different purposes. For example, NIOSH acts under the authority of the Occupational Safety and Health Act of 1970 and develops Recommended Exposure Limits (RELs) for hazardous substances that are found in the workplace. RELs are intended to limit the concentration of the potential hazard in the workplace air to protect worker health. As stated on the NIOSH website (http://www.cdc.gov/niosh/topics/cancer/pdfs/1995_NIOSHRELpolicy.pdf), NIOSH RELs are based on risk evaluations using human or animal health effects data, and on an assessment of what levels can be feasibly achieved by engineering controls and measured by analytical techniques. OSHA's Permissible Exposure Limits (PELs) are issued in response to a mandate under the Occupational Safety and Health (OSH) Act of 1970. As stated on their website (<https://www.osha.gov/dsg/topics/pel/>), OSHA sets enforceable PELs to protect workers against the health effects from airborne exposure to hazardous substances. OSHA PELs are based on 8-hour exposures in the workplace. While values derived by other federal agencies may be appropriate for the workplace, for example, EPA's mandate is for public health which is a broader and, for vulnerable populations, a more complex undertaking.

b. What IRIS users/customers are calling for these new assessments?

Answer: IRIS assessments are the scientific foundation for EPA decisions to protect public health, and our primary clients are the program and regional offices who nominate chemicals for addition to the IRIS agenda. For example, IRIS is the first source of toxicity information used by the agency to make decisions and set cleanup levels.

c. Given that "science is science," why is an IRIS assessment superior to other assessments, including those of professional societies and industry?

Answer: The IRIS Program provides high quality, publicly available information on the toxicity of chemicals to which the public might be exposed. As indicated above, EPA's IRIS Program is the only federal program devoted solely to the evaluation of health hazard and dose response information for the purposes of developing cancer and noncancer chronic toxicity values for the oral and inhalation pathways of exposure. IRIS assessments undergo a very rigorous review process, involving the public and stakeholders at various steps in the assessment development process, as well as internal agency scientists, scientists from other federal agencies, and rigorous independent external peer review.

15. You have implemented a standing set of bi-monthly meetings to address chemical specific scientific issues as well as to have discussions about problem formulation. At the most recent June meeting, it appeared that many NGOs boycotted the meeting due to concerns they said were related to not knowing about the meetings and concerns regarding too much industry representation. It is our understanding that these meetings

have all been announced on the IRIS webpage, registration is open to everyone, and anyone who wishes to speak can get a slot on the agenda. Is this a fair representation of your actions to ensure that all representatives of the public are welcome to provide an input to the IRIS process, or do the arguments for the boycott have merit?

Answer: Yes – this is a fair representation of our actions to ensure the public has the opportunity to participate in our meetings. The IRIS Program welcomes anyone who is interested in participating or discussing scientific issues at our public meetings. We recognize that obtaining different perspectives on scientific issues is important, and for that reason, we have been exploring new mechanisms to invite scientists who might be interested in scientific topics to our meetings. We also recognize that not all of our stakeholders have the resources to travel to Washington, DC, to participate in a meeting. For the past year and a half, every public meeting held by the IRIS Program has also been available by webinar. This has been a successful model in that we often have 50-100 individuals participating by webinar from outside of Washington, DC. We are working to better ensure that webinar participants can more fully engage in our meetings, including encouraging webinar participants to actively participate in discussions remotely (i.e., via telephone). EPA also moderates these discussions to facilitate equal participation among both virtual and in-person attendees.

16. Should standard protocols be developed to enable all studies to be independently judged based on their quality, strength, and relevance, regardless of the author affiliation or funding source? If so, will you make development of these standard approaches a priority?

Answer: We have fully embraced the concepts of systematic review, and are committed to implementing the principles of systematic review in IRIS assessments as recommended by the NRC. The refinement of standard protocols to independently and transparently judge the quality and strength of a study identified through a literature search is a priority for the IRIS Program. In their 2014 review of the IRIS Process, the NRC recommended that evidence evaluation and risk-of-bias analysis be conducted using methods that are “transparent, reproducible, and scientifically defensible.” The NRC also recommended that funding sources be considered in systematic reviews conducted for IRIS assessments. These topics will be discussed with systematic review experts and the public at an upcoming IRIS workshop on the 2014 NRC recommendations to be held October 15-16, 2014.

17. The science of hazard assessments has become complex in recent years. Does IRIS have the requisite staff and expertise in all the needed disciplines to draft assessments efficiently and quickly? Would a more qualified staff lead to more concise and accurate assessments, partially because much of the information in these 1,000+ page assessments could be eliminated?

Answer: Yes, IRIS staff have expertise in the disciplines necessary to develop quality assessments quickly and efficiently. Aided by the 2013 enhancements to the IRIS process, the capacity of IRIS staff to draft assessments will benefit from increased upfront planning and early engagement with stakeholders and the public. The distribution of preliminary materials and early discussion of scientific issues will help IRIS staff better understand

differing viewpoints and allow for those issues to be better presented in draft assessments. Along with the public and stakeholder interaction that occurs at the bimonthly public science meetings, the IRIS Program is developing a means of augmenting the scientific expertise available during these public meetings with eminent scientific experts identified by the NRC. These individuals will help ensure scientific issues are properly and more fully addressed early in draft development.

18. Following up on our discussion in the hearing when you said you would get back to the Committee with specifics, do you anticipate the first couple of IRIS assessments that will incorporate all of the NRC recommendations to be on new chemicals, and if so, which ones, or will they be updates of old assessments?

Answer: I stated that it would be 3-5 years before we complete implementation of all the NRC recommendations. Given those timelines, we anticipate that the first assessments to fully incorporate all the NRC recommendations will be inorganic arsenic and formaldehyde.

19. How does EPA intend to approach more challenging IRIS reforms such as evidence integration and weight of evidence? When will EPA develop guidelines or integrate a consistent approach in actual assessments?

Answer: The IRIS Program is working toward developing standardized systematic review methods for selecting and evaluating studies as well as methodologies for evidence integration and weight-of-evidence determinations. To move forward in this area, in August 2013, the EPA convened a public scientific workshop focused on approaches for evaluating individual studies, synthesizing evidence within a particular discipline, and integrating evidence across different disciplines to draw scientific conclusions and causality determinations. Another workshop will be held on October 15-16, 2014, to discuss systematic integration of evidence streams from human, animal, and mechanistic studies, as recommended by the NRC in their 2014 review of the IRIS process.

Also in 2013, the IRIS Program began development of a handbook to describe standard protocols and processes for staff to use when developing an IRIS assessment. This draft handbook represented our initial thoughts on several topics relevant to systematic review, including evidence integration and evaluating the evidence for a given effect. The draft handbook was provided to the NRC committee reviewing the IRIS process to inform their deliberations. The NRC noted in the 2014 report that elements of the draft handbook address many of the concerns over evidence evaluation raised by the NRC formaldehyde report. At the same time, the NRC encouraged further development and completion of the handbook as the IRIS program identifies best practices that facilitate the application of systematic review to IRIS assessments. Development of the draft handbook is ongoing.

The IRIS Program is continuing to evolve and the more challenging reforms noted above are under active consideration by the program. The 2014 NRC report commended the agency's efforts to improve the IRIS Program, and that the program had made substantial progress in the short time since release of the formaldehyde report. The IRIS Program anticipates that

completion of the recommendations presented in the 2011 and 2014 reports, including those on evidence integration, will be completed in three to five years.

20. The testimony from Mr. Walls noted that even though EPA documents are peer reviewed, the EPA staff that write the assessments are judge and jury of which comments from the public and from peer review experts are accepted and rejected. In fact, it was brought to our attention that in the recently finalized methanol document, EPA staff used the response to comments to describe a new policy position and approach to address endogenous exposures.

- a. Do you support such actions? Should there be an independent entity, similar to the role a journal editor plays, to review how EPA staff respond to comments before the document is finalized?**

Answer: Public comment and robust expert peer review is an important part of the agency's scientific work, and responding to public and peer review comments is an important step in completing a scientific product. It is not our intention to incorporate new policy positions in responses to comments. A core value of the IRIS Program is to appropriately address comments received from the public and external peer review. Following external peer review, EPA revises draft IRIS assessments to respond to public and peer review comments. The revised draft assessment is then reviewed by agency scientists who do not work in the IRIS Program; additionally, it is reviewed by scientists from other federal agencies and the Executive Office of the President. Each IRIS assessment documents the responses to public and peer review comments in an appendix that is publicly available. With the 2013 IRIS enhancements, EPA established a new Science Advisory Board (SAB) Chemical Assessment Advisory Committee (CAAC). The CAAC will provide independent review of IRIS assessments. A significant benefit to the IRIS Program from the standing SAB panel is the continuity it will provide across multiple assessments, and the capability to ensure that peer review comments across assessments are similarly and adequately addressed.

21. The National Research Council recommends that the IRIS handbook be peer reviewed. Has this happened? Will it? If so, when, and if not, why not?

Answer: No, the IRIS handbook has not yet been peer reviewed because it is still under development as we consider the recommendations of the NRC's 2014 report, and consider forthcoming discussions on their recommendations at the upcoming October 15-16 IRIS workshop. The handbook will be peer reviewed in the future, but the form of the peer-review may vary depending on how the handbook is developed. The handbook is considered to be an evolving, "evergreen" document that will be updated to incorporate new approaches when the IRIS Program identifies best practices in applying systematic review to IRIS assessments. At this time, we anticipate that as parts of the handbook are completed and implemented in the development of a given chemical assessment, they will be sent for peer review along with the assessment. In this way, the handbook in its entirety would be peer reviewed. Portions of the handbook may also be discussed at IRIS bimonthly public science meetings to gather additional feedback.

22. You have recently developed a subpanel of the EPA Science Advisory Board to review IRIS assessments.

- a. Will this panel be asked to review cross-cutting issues, like assessments of chemicals below background or endogenous exposures?**

Answer: Yes the CAAC will be consulted on cross-cutting scientific issues in the course of their assessment reviews.

- a. Will you take public comment on the "charge questions" asked of this panel?**

Answer: Yes. As part of the IRIS enhancements, in step 4 of the IRIS process, the draft assessment and a draft of the peer review charge are released for public comment and discussion at an IRIS public science meeting. The draft charge or assessment may be revised prior to being released to peer review in order to be responsive to public comments.

- c. Consistent with the Environmental Research, Development, and Demonstration Authorization Act, which authorizes the Science Advisory Board, will you allow this panel to answer any and all questions sent by this Committee?**

Answer: The SAB is a federal advisory committee established by the EPA Administrator and, as with all EPA federal advisory committees, is subject to "administrative guidelines and management controls" established by the EPA Administrator. (See, FACA section 8(a)). As required by FACA, the EPA Designated Federal Official calls each meeting and approves the agenda for each meeting.

EPA and staff of the House Science, Space and Technology committee are developing a process for managing questions on which the specific congressional committees would like SAB advice.

23. The National Research Council recommends that EPA should provide technical assistance to stakeholders who don't have resources to provide input. How is EPA implementing or planning to implement this proposal fairly so that one class of stakeholders isn't overly assisted?

Answer: In the 2014 NRC review of the IRIS process, the committees commended our initiatives to engage with stakeholders and the public, while noting that differences in scientific and financial resources may contribute to an imbalance in public input to the IRIS Program. The IRIS Program already conducts significant outreach activities to ensure that potential stakeholders are made aware of upcoming IRIS activities. These activities include the use of webinars to expand access to individuals unable to travel to the D.C. area; email and social media, particularly to professional societies and disease interest groups; and IRIS

and Human Health Risk Assessment program bulletins that are sent to several thousand individuals. Reaching out through a variety of methods broadens the array of stakeholders and helps to ensure that no one group of stakeholders is uninformed.

Additionally, the IRIS Program is developing a proposal by which technical assistance can be provided through the National Research Council. The intent of this proposal is to engage the NRC to identify, evaluate, and arrange for scientific experts to participate in IRIS public meetings. The primary benefits of this arrangement are that it is expected to improve access to subject matter experts and provide a wider range of scientific perspectives. Individuals participating through this NRC augmentation of the IRIS public science meetings will not represent any specific group of stakeholders, but their presence will enhance and focus public discussion on key scientific issues. The IRIS Program anticipates that access to these subject matter experts early in the assessment development process will also enhance the quality of IRIS assessments.

Responses by Dr. Ms. Rena Steinzor

Questions submitted by Chairman Broun and Chairman Schweikert

1. To what extent does having multiple toxicity assessment sources for the same chemical present challenges for ensuring consistent risk management across the nation, and what steps should EPA take to either minimize or explain reasons for any differences?

A number of different offices within the federal government, at the state government level, and at the international level produce hazard- and risk-assessment documents that factor into risk management decisions. It is important that each of these programs operate independently, for a variety of reasons. Each is developed through a unique process, looking at different evidence bases, and developed by a unique set of experts for a specific purpose.

The following chart highlights a few reasons why a handful of federal programs each have value-added for risk managers:

<i>Program</i>	<i>Value-added</i>
IRIS	<ul style="list-style-type: none"> • Carcinogen hazard identification and dose-response assessments most useful to EPA program offices • IRIS profiles present actionable numbers (inhalation RfDs, oral RfCs) • Assessments used by state and federal regulatory officials
Report on Carcinogens	<ul style="list-style-type: none"> • Simplified assessment of carcinogenic potential – good starting point for the general public (including businesses seeking to “green” their production – see www.chemhat.org)
ATSDR	<ul style="list-style-type: none"> • Provides exposure assessments for environmental toxins • Site-based assessments that address multiple hazards • Public health advisories (e.g., case of contaminated groundwater flooding basements and leaving Cr(VI) deposits – does not rise to top of Superfund priorities, but ATSDR provided helpful advice) (see attached InsideEPA article)
NIOSH	<ul style="list-style-type: none"> • Specific focus on workers’ exposures, so priority chemicals are different than those in the programs listed above • All NIOSHA risk assessments are conducted according to agency’s “Research to Practice” mission, so publications include Recommended Exposure Levels (aimed at reducing significant risks over a working lifetime) and practical information about hazard elimination and reduction through a hierarchy of controls.

No one group—be it EPA or the World Health Organization or California’s Office of Environmental Health Hazard Assessment—should be forced to align its assessment with ones done by a different agency or department for different purposes. In fact, such outcome-focused review of the evidence would contradict principles of good science. While an organization’s explanation of the difference between its assessment and others’ assessments may provide some value in terms of accessibility to lay readers, it is far more important that these groups clearly describe their methods and information sources (as IRIS does), so that experts can reach their own conclusions about the relative strengths and weaknesses of the different assessments.

2. As you know, Dr. Ken Olden at EPA has implemented a standing set of bi-monthly meetings to address chemical-specific scientific issues as well as to have discussions about problem formulation. At the most recent June meeting, it appeared that many NGOs boycotted the meeting due to concerns they said were related to not knowing about the meetings and concerns regarding too much industry representation. It is our understanding that these meetings have all been announced on the IRIS webpage, registration is open to everyone, and anyone who wishes to speak can get a slot on the agenda. Do you support the NGOs’ call for a boycott?

Dr. Olden has significantly expanded the IRIS program’s stakeholder engagement. However, increased stakeholder engagement is not good public policy, per se. As the NRC committee noted in its recent report on the IRIS program,¹ simply increasing the number of opportunities for stakeholder involvement favors the stakeholders with the greatest resources. This notion is backed by empirical research regarding other EPA programs.² Professor Wendy Wagner conducted such research and concluded:

a number of doctrinal refinements [to administrative law], originally intended to ensure that executive branch decisions are made in the sunlight, inadvertently create incentives for participants to overwhelm the administrative system with complex information, causing many of the decisionmaking processes to remain, for all practical purposes, in the dark. As these agency decisions become increasingly obscure to all but the most well-informed insiders, administrative accountability is undermined as entire sectors of affected parties find they can no longer afford to participate in this expensive system. Pluralistic oversight, productive judicial review, and opportunities for intelligent agency decisionmaking are all put under significant strain in a system that refuses to manage—and indeed tends to encourage—excessive information.³

The toxicologists and environmental scientists who wrote an open letter to the IRIS program’s top management to express their views about the June 2014 inorganic arsenic and hexavalent chromium meeting did a great service by shining a light on the measurable impacts of simply increasing the number of opportunities for stakeholders to engage in the IRIS process without actively engaging a broad set of interested parties. The NRC committee that reviewed the IRIS process made a valuable recommendation that would address these problems in the IRIS program and deserves Congress’s

¹ National Research Council of the National Academies, REVIEW OF EPA’S INTEGRATED RISK INFORMATION SYSTEM (IRIS) PROCESS (May 2014).

² See, Wendy E. Wagner, *Administrative Law, Filter Failure, and Information Capture*, 59 DUKE L. J. 1321 (2010)

³ *Id.*

support. The committee suggested:

One way to ensure broad stakeholder input would be to provide technical assistance to enable under-resourced stakeholders to develop and provide input to the IRIS program; this could be modeled after other EPA technical-assistance programs. For example, EPA's Superfund program has a long history of providing technical assistance in the form of grants and more recently direct consultation to neighbors of sites on the National Priorities List. The grants generally improve the process of remedial decision-making by ensuring that the affected public understands both the characterization and the remediation of hazardous-waste contamination and by making it easier for such people to provide constructive input.⁴

Questions Submitted by Environment Subcommittee Ranking Member Suzanne Bonamici

1) On January 9th of this year, approximately 10,000 gallons of Methylcyclohexane-Methanol (MCHM) began spilling into the Elk River in West Virginia. About 300,000 people were left without access to clean drinking water for days. It took the company that developed the chemical more than a week to publicly release toxicology studies. Another five days passed before regulators discovered that a new chemical, propylene glycol phenyl ether (PPH), was also present in the tanks. Far from an isolated incident, spills within the last two years in Ohio, Texas, North Dakota, Wisconsin, Oklahoma, and Georgia highlight two important considerations: It is critically important that state agencies and the public have information to inform response decisions to chemical spills. It is also clear that industry is in no hurry to provide that information freely.

a) Does continued secrecy from industry regarding the safety of their products endanger the public?

As I noted in my written and oral testimony, the Freedom Industries spill is a striking example of all that can go wrong when we shrink government public health functions and rely on private industry to protect us from harm. The company's failure to release immediately all toxicology studies on the chemicals that it stored at the facility is deplorable. Unfortunately, such behavior is effectively condoned, given the yawning gap in protections under the Emergency Planning and Community Right-to-Know Act (EPCRA) and the Toxic Substance Control Act (TSCA). TSCA, as implemented by EPA, requires chemical manufacturers to disclose some basic toxicological information about chemicals before they go on the market. However, tens of thousands of chemicals, including crude MCHM, were already in commerce and "grandfathered in" when Congress passed TSCA in 1976. In other words, the companies that produce and use the chemical had no obligation to develop toxicity studies when TSCA took effect—crude MCHM was presumed safe enough. Similarly, EPCRA established some protections against public health threats, but does not cover crude MCHM. Any company that stores crude MCHM (or any of thousands of other chemicals) must report to local authorities how much of that chemical they have stored, and where. But since crude MCHM was not previously identified as "extremely hazardous" by federal officials, local officials did not have to develop plans for a potential leak.

This situation points up the other critical factor in city of Charleston's public health emergency

⁴ National Research Council of the National Academies, REVIEW OF EPA'S INTEGRATED RISK INFORMATION SYSTEM (IRIS) PROCESS, 23 (May 2014).

following the Freedom Industries spill. The state public health department (the West Virginia Bureau of Public Health) is underfunded and understaffed. A recent assessment of the department's capacity by federal experts from the Centers for Disease Control includes several striking points:

- **Five** of the 34 epidemiology positions (15 percent) at the Bureau of Public Health (BPH) are currently vacant.
- BPH has failed to adequately plan for the many types of natural and man-made disasters that could potentially affect West Virginia residents.
- The epidemiologic investigation of the Freedom Industries spill took over six weeks, involved over a dozen staff, and required hundreds of hours of their time.
- BPH employs no epidemiologists in positions assigned to respond to acute chemical or radiological releases, or specifically tasked with natural disaster response.
- BPH has no programs to enhance occupational safety and health of responders.⁵

In this context, industry secrecy regarding basic toxicological information is a major public health threat.

- b) Does the lack of transparency by industry make an even stronger case for a functioning IRIS?

The IRIS program could partially bridge the gap between EPCRA and TSCA, if it were properly funded. IRIS staff has broad authority to develop hazard assessments for any chemical in commerce. In an ideal world, where the IRIS program has unlimited resources, IRIS staff would collect and assess the available information on the tens of thousands of chemicals that have not undergone TSCA-based reviews and publish those assessments in its widely accessible web database. In the real world, however, the IRIS program operates under significant resource constraints. With its available resources, most of the IRIS agenda centers on developing assessments for EPA's regulatory program offices (e.g., the Office of Water or the Superfund program), with little room for assessing emerging public health threats. Nevertheless, the IRIS program has the flexibility to prioritize assessments for chemicals that are stored, used, produced, or transported in significant quantities in communities that are overburdened by toxic chemicals and socioeconomic stressors. For one approach to that kind of agenda-setting process, please refer to the Center for Progressive Reform paper, *Setting Priorities for IRIS: 47 Chemicals that Should Move to the Head of the Risk-Assessment Line*,⁶ which is attached to my written testimony.

2) You have written reports on the tactics used by industry to stall the publication of IRIS health assessments. What kind of tactics have you seen employed by industry in this area? What conclusions have you reached regarding the willingness of industry to

⁵ Letter from Mary Anne Duncan, DVM, MPH, Epidemiologist and Assessment of Chemical Exposures (ACE) Program Coordinator, Division of Toxicology and Human Health Sciences, Agency for Toxic Substances and Disease Registry, to Loretta E. Haddy, PhD, MS, West Virginia State Epidemiologist and Director of Office of Epidemiology and Prevention Services (Aug. 18, 2014), available at <http://media.wvgazette.com/static/watchdog/CDC%20Training%20Memo.pdf>.

⁶ Available at http://www.progressivereform.org/articles/IRIS_Priorities_1010.pdf.

spend millions of dollars to delay and discredit IRIS assessments?

The chemical industry's advocates are skilled, knowledgeable, and well-connected—and they completely outgun public interest advocates. The two overarching strategies that I have observed the chemical industry employ for years are (1) fund research to increase uncertainty about each facet of a chemical risk assessment, and (2) foster a sense of distrust about the programs and processes for developing those risk assessments. Some examples of the chemical industry's efforts to pursue these strategies include:

- IRIS staff have been working on new hazard assessments for hexavalent chromium (Cr(VI)) for a number of years. After they set their work in motion, the American Chemistry Council started a multi-year research program dedicated to exploring issues related to the mode of action for chromium toxicity. A better understanding of toxicological modes of action is helpful, to be sure, but ACC has used this ongoing research program as an excuse to demand that the IRIS program slow down its development of new hazard assessments for Cr(VI). Meanwhile, millions of U.S. residents are exposed to the chemical in drinking water or through food, driving home the need for solid risk assessments that will enable risk managers to do their jobs.
- A constant stream of reports from the Government Accountability Office (GAO) and the National Academies' National Research Council (NRC) maintain a sense that the IRIS program is scuffling and struggling to develop high quality assessments. The people who write these reports are respectable professionals, so their assessments of the IRIS program are fair and balanced, generally noting both the strengths and weaknesses of the IRIS program. However, the criticisms in the reports get the most attention and help the chemical industry build a case for constantly revising the processes by which IRIS staff develop new assessments. While IRIS leadership profess that program and management changes are designed to have little effect on output, the results are clear. Production of final assessments has dropped dramatically in recent years.

The chemical industry can—and does—spend millions of dollars on research and advocacy to slow the IRIS process. Without new assessments, the public, policymakers, and risk managers are left without adequate information to properly control the chemicals that pervade our lives.

GROUNDWATER 'INTRUSION' SPURS EPA TO WEIGH EXPANDED NPL LISTING POLICY
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HEADLINE: GROUNDWATER 'INTRUSION' SPURS EPA TO WEIGH EXPANDED NPL LISTING POLICY

BODY:

EPA officials are weighing whether to expand the scope of their proposed changes to the Superfund Hazard Ranking System (HRS) to allow sites that have toxic liquids and solids seeping into buildings from groundwater to be eligible for Superfund listing -- in addition to listing sites where toxic vapors may be a source of concern.

The proposition is being sparked by a unique case in New Jersey where groundwater flooding into local basements is leaving behind hexavalent chromium (Cr6) crystals, but officials are unable to place the site on the Superfund National Priorities List (NPL) because of the agency's current policy preference for weighing exposure to contaminated drinking water sources.

But officials may have to be careful about how they frame any additions to the potential rulemaking since it may encourage other groups to push for changes to the HRS -- the scoring system that evaluates whether sites should be placed on the NPL and made eligible for federal cleanup funding -- such as including explosive materials as a pathway to listing. The HRS is a numerically based screening system that uses information from preliminary assessment and site inspections to assess the relative potential of sites to pose a threat to human health or the environment.

EPA is weighing whether to launch a rulemaking to amend the HRS to account for exposure to "vapor intrusion" from underground sources of contamination. EPA is considering the issue at the recommendation of the Government Accountability Office (GAO), which encouraged the agency to address the issue in a report released last year. Among other things, GAO found that an additional 37 sites would be added to the Superfund list if vapor intrusion was added to the HRS, although it did not say which sites those were.

The agency published a notice in the Federal Register Jan. 31 asking for comment on the "Potential Addition of Vapor Intrusion Component to the Hazard Ranking System," saying EPA is only considering "a proposed rulemaking to add a vapor intrusion component to the HRS" and is seeking comment on if and how it should do so. Intrusion of solids and liquids is not mentioned

in the notice.

But at a Feb. 24 listening session on the agency's plan to add vapor intrusion to the HRS, Dennis Munhall of EPA Region II told Inside EPA that the agency is also weighing exposure pathways to liquids and solids in an attempt to head off what could be an "emerging problem."

The proposed expansion stems from a groundwater plume under Garfield, NJ, which is contaminated with Cr6, the result of a 1983 discharge of roughly 5,441 pounds of the metal from the E.C. Electroplating site. Despite monitoring, the plume was never fully cleaned up.

In recent years, yellow dust began appearing in local basements, deposited there by flooding groundwater. Last September, the Agency for Toxic Substances & Disease Registry (ATSDR) issued a public health advisory recommending "that U.S. EPA take short- and long-term measures to dissociate persons -- whether in residential or commercial properties in the area of the contaminant plume -- from hexavalent chromium exposures resulting from infiltration of contaminated groundwater into the basements of these properties."

ASTDR further recommends that EPA in the long term "remediate permanently" the groundwater plume. "In the absence of a permanent solution, all residents within that groundwater contamination plume could continue to be exposed to hexavalent chromium," according to the health advisory. "And that exposure could be at levels that present an immediate and significant health threat."

Region II's Office of Emergency Response is addressing the most immediate contamination as officials grapple with a long-term solution.

The region is now looking at listing the site on the NPL, Munhall said, but is having trouble determining how to rank it through the existing pathways. Since residents are all on a public water system, which is piped in from uncontaminated wells, and the groundwater isn't being used, Region II officials are unclear if the site can be added to the NPL on that pathway.

One lawyer familiar with the Superfund program says that it's likely that the site would not score high enough on the HRS through the groundwater pathway to land on the Superfund list because drinking water supplies aren't being threatened. The HRS is heavily weighted towards protecting drinking water and since residents are on a clean public water supply, the potential for exposure as laid out in the current scoring system is minimal.

When the HRS was being drafted, officials "never considered people getting in contact with groundwater" other than through drinking it, the source says. "Because everything is focused on drinking water, the presence of public water changes things enormously," the source adds, noting that sites with vapor intrusion are blocked from the NPL for largely similar reasons.

While the agency could use ASTDR's public health advisory and recommendation to seek listing -- a rarely used method for placing sites on the NPL -- that would not help similar sites in the future. Munhall said he did not know of any other site where intrusion of solids or liquids is threatening public health, but added "if it's happening here, my guess is it's happening elsewhere."

Munhall said the region is looking into all options including the potential rulemaking to add vapor

intrusion to the HRS -- the first time the regulation has been amended in 20 years -- for possible relief.

At the Feb. 24 listening session, agency officials insisted that no decisions have been made on how or whether to move forward with the rulemaking or make changes through guidance, if anything issued would include solids and liquids or what such language would look like.

The seven commenters at the meeting -- comprising representatives from the Edison Wetlands Association, Center for Health, Environment and Justice and residents of Pompton Lakes, NJ, and Ashville, NC -- all supported the addition of vapor intrusion on the HRS, arguing that the change would "put some teeth" into addressing affected sites and ensure better protection of human health.

However, the lawyer familiar with Superfund issues says EPA would be better off issuing a guidance document that allows for sites to be ranked on vapor intrusion through the air and groundwater pathways in order to avoid the "scrutiny" of a formal rulemaking and political pressure from Congress. Furthermore, the source adds, the agency should set a national toxicity standard for the chlorinated hydrocarbons most often associated with vapor intrusion and require evaluations to be done as a criteria for funding for state Superfund response programs.

In addition, a rule would likely not be ready until 2012, an election year when politicians will be reluctant to push through a potentially controversial regulation, that is if the rulemaking does not lose funding from regulation-leery Republicans before a final rule is prepared.

EPA is accepting comments until April 16 and will hold two more listening sessions, the first March 16 in San Francisco and the second March 30 in Albuquerque, NM. -- Jenny Hopkinson

Responses by Dr. Mr. Michael P. Walls

QUESTIONS FOR THE RECORD

Submitted by

Chairman Broun and Chairman Schweikert

to

Mr. Michael P. Walls

Vice President, Regulatory and Technical Affairs, American Chemistry Council

1. Many other federal agencies—including the National Institutes of Health, Occupational Safety and Health Administration, Centers for Disease Control and Prevention, and other parts of the Environmental Protection Agency (EPA)—also conduct chemical risk assessments. Could the NRC's 2014 report's recommendations be applied to all federal chemical risk assessment programs, and should they? Further, could the recommendations in Chapter 7 of the NRC's 2011 formaldehyde report be applied to all federal chemical risk assessment programs, and should they?
 - A. Other similar federal chemical hazard and risk assessment programs can and should apply the National Academy of Sciences (NAS) recommendations reflected in the 2011 and 2014 studies. All of the individual NAS recommendations, however, may not be relevant to every chemical risk assessment program or even to specific risk assessments. Some assessment programs, for example, may initially conduct fairly rapid, screening level assessments that purposely rely on default conservative assumptions to determine whether estimated risks fall below a health concern.

If the screening evaluation indicates a potential for concern, then the knowledge gained in the screening evaluation can then be used to identify the determinants that need to be evaluated with more precision in a refined assessment to enable risks at environmentally relevant exposures to be characterized with a greater degree of certainty. In this example, the NAS recommendations would most aptly apply to the refined assessments. The specifics of a governmental assessment program, its approach, and its goals will be factors in determining the relevance of the individual NAS recommendations.
2. To what extent does having multiple toxicity assessment sources for the same chemical present challenges for ensuring consistent risk management across the nation, and what steps should EPA take to either minimize or explain reasons for any differences?
 - A. The real challenge for risk management is the development of Integrated Risk Information System (IRIS) assessments that provide overly conservative point estimates to be applied in all situations. In ACC's view, the IRIS program should provide a range of plausible risk estimates that reflects scientific reality, clearly explains uncertainties and limitations, and is useful for multiple risk management scenarios.

A recommendation made in the 2014 NAS report directs the IRIS program to stop developing only upper bound (or high end) estimates of reference doses (RfDs)

and cancer potency slopes (CPS) and, instead, include central estimates. Central estimates are more indicative of the average or center of a distribution. A recent study has shown that when central estimates of exposures are used, the risk estimates are almost 30 times lower than those based on high end values.¹ For Superfund site remediation, for example, the authors of that study concluded that over 40 percent of sites would be viewed as being in the discretionary cleanup range. If EPA used central estimates of RfDs and CPS along with central estimates of exposures, the calculated risks would be even lower. EPA should hold IRIS to the standard of producing the most scientifically accurate and objective risk information achievable.

Multiple toxicity assessments may create challenges for some risk managers. In most risk management scenarios, it would be useful to have assessments that provide alternatives to an IRIS value. ACC has suggested that IRIS assessments include a section that describes why an IRIS value may differ from values provided by other programs or earlier IRIS assessments.

The best use of government resources would ensure that the multiple assessment programs that exist are well coordinated and efficiently use their resources to develop scientifically robust assessments. In ACC's view, two necessary steps for improving assessments are: (a) using pre-defined criteria to judge the strength and quality of all relevant information and (b) integrating the information in a manner that takes into account the quality of the evidence, considers the strengths and limitations of the evidence, and transparently explains how the various types of evidence fit together. In addition, all federal programs should use up-to-date knowledge of mode of action in lieu of default assumptions and should focus on evaluating hazards and risks at exposure levels relevant to the health of Americans and the U.S. environment.

3. Which IRIS assessments should EPA address as soon as possible, and why?

- A. The IRIS program should be assessing chemicals for which there are significant uses and potential exposures within U.S. non-occupational populations. Because IRIS assessments take significant time and resources to develop and complete, the program should focus on those chemicals for which there are robust scientific databases and complex scientific questions that require the integration of data from multiple evidence streams. The IRIS program should provide clearly articulated rationales for assessing these substances.

The last time EPA solicited public input on chemical nominations for IRIS was October 18, 2010, when the Agency was preparing the 2011 IRIS agenda. EPA never formally released the results of that solicitation and Agency review process, and they have not released an updated IRIS agenda. EPA does place some information on its

¹JOURNAL OF ENVIRONMENTAL ECONOMICS AND MANAGEMENT 34, 187-206 (1997).
ARTICLE NO. EE971012 http://law.vanderbilt.edu/files/archive/183_Conervative_versus_Mean_Risk.pdf.

web-based tool, IRISTrack, but ACC understands that the tracking tool has been in the process of an overhaul for over a year. Notably, IRISTrack does not provide information on the rationale for adding or removing chemicals to/from the IRIS agenda. The IRIS program should engage stakeholders in a dialogue to determine and set IRIS priorities.

4. As you know, Dr. Ken Olden at EPA has implemented a standing set of bi-monthly meetings to address chemical specific scientific issues as well as to have discussions about problem formulation. At the most recent June meeting, it appeared that many NGOs boycotted the meeting due to concerns they said were related to not knowing about the meetings and concerns regarding too much industry representation. It is our understanding that these meetings have all been announced on the IRIS webpage, registration is open to everyone, and anyone who wishes to speak can get a slot on the agenda. Do you support the NGOs' call for a boycott?
 - A. No. ACC does not support boycotts of scientific discussions that are open to any stakeholder that wishes to participate. The dates for the IRIS bi-monthly meetings are announced in the Federal Register, EPA updates the dates on the IRIS webpage, and, as noted in the question, the meetings are open to all who wish to participate. Dr. Olden's approach to engage stakeholders early in scientific discussions should help to improve the scientific rigor of the assessments and also help IRIS complete assessments more quickly by identifying and addressing potential issues earlier in the process.
5. In its report, the NRC recommends that EPA should provide technical assistance to stakeholders who don't have resources to provide input. Do you have any concerns about such a practice?
 - A. Technical assistance provided by EPA can benefit many diverse stakeholder groups. EPA should provide information on any technical assistance it provides to stakeholders and should make the information available to all stakeholders using Federal Register notifications and public EPA dockets. Where such technical assistance covers areas of scientific debate, EPA should provide information on alternative interpretations, methodologies, or data, as appropriate.
6. The NRC recently completed its review of the National Toxicology Program's (NTP) listing of formaldehyde in the 12th Report on Carcinogens. In its report, the panel concurred with the NTP's listing of formaldehyde as "known to be a human carcinogen," and it also found "clear and convincing" evidence of "an association between formaldehyde exposure and myeloid leukemia." This is a very different conclusion than the one found by the NRC panel in 2011 which did not find a causal link between formaldehyde exposure and leukemia. What impact could these seemingly conflicting reports have on stakeholders and the public?
 - A. We find it concerning that the 2014 NRC Committee's review of the formaldehyde

listing in the 12th Report on Carcinogens (RoC) is quite different than the 2011 NRC Committee's review of the EPA draft IRIS assessment for formaldehyde. The 2011 NRC Committee did not simply review and comment on EPA's methodology, but it also made substantive comments regarding the following:

- The limitations and inconsistencies of the epidemiological data, calling it "inconsistent" and "highly variable" (NRC 2011, at p. 111)
- The "paucity of formaldehyde-induced LHP cancers in animal models" (NRC 2011, at p. 110)
- The fact that there is "little known about a potential mode of action" (NRC 2011, at p. 7)

Notably, the 2011 NRC Committee made these substantive conclusions after reviewing a formaldehyde database similar to the one that the NTP reviewed for the 12th RoC. The significant divergence between the two NRC Committees' interpretations of the science raises further questions instead of answering them. It also reinforces the need for a comprehensive and fully integrated analysis of formaldehyde. Unfortunately, the 2014 NRC Committee was not charged to undertake a fully integrated analysis in its review of the 12th RoC formaldehyde listing.

The 2014 NRC Committee review of the formaldehyde listing in the 12th RoC must be viewed in context—it was a narrow review that focused solely on applying the NTP listing criteria. The NTP listing criteria lack the rigor necessary to support a credible hazard assessment, as they do not take into account the totality of the evidence nor do they integrate all studies when making a hazard determination. Separate NRC Committee reports on formaldehyde and the IRIS program published in 2011 and 2014, respectively, recommend these measures. This NRC Committee did not consider negative studies and inconsistent findings across studies and within individual studies, as they were not considered relevant to informing the listing. This consideration, or lack thereof, is particularly troubling given formaldehyde's rich and extensive scientific database, which requires a fully integrated review.

Moreover, the 12th RoC is a hazard assessment and, therefore, does not assess potential risks from typical exposures to potential carcinogens. It does not consider real world exposures to assess human health risks. Formaldehyde has been reviewed at the federal level, and its use is subject to regulation in consumer products and in the workplace to control exposures and to ensure public health. The scientific literature is clear that there is no increased health risk from low-level exposures normally found in home or work environments.

Ultimately, the 2011 and 2014 NRC Committee reports on the formaldehyde IRIS assessment and the larger IRIS program should inform how future hazard and risk assessments for formaldehyde and other chemicals are conducted. As EPA finalizes its revised IRIS assessment, we urge EPA to refer to these reports to ensure their analysis considers all of the available data, as well as its strengths and weaknesses, and is more integrated than the one provided in the formaldehyde listing in the 12th RoC.

Appendix II

ADDITIONAL MATERIAL FOR THE RECORD

PREPARED STATEMENT OF FULL COMMITTEE RANKING MEMBER
EDDIE BERNICE JOHNSON

Thank you Mr. Chairman. Virtually every aspect of our daily lives is impacted by the use and presence of chemicals. The goal of the Integrated Risk Information System (IRIS) at EPA is to provide information to the American people about the risks associated with exposure to certain chemicals. It should be obvious to anyone that information about the health effects of chemical exposures can only benefit the public. Unfortunately, the value of IRIS is too often obscured by the criticisms of those who stand to gain by interfering with EPA's mission to protect human health and the environment.

The National Academies report released this May praises the substantial improvement made by EPA in addressing issues that had been raised about the IRIS process. Specifically, the report states that if EPA continues on this path of improvement, "the IRIS process will become much more effective and efficient in achieving its basic goal of developing human-health assessments that can provide the scientific foundation for ensuring that risks posed to public health by chemicals are assessed and managed properly." The report also points out two important future steps which EPA can take to further improve the quality of their IRIS assessments.

First, EPA must continue to expand opportunities for stakeholder input and discussion. The chemical industry is not the only stakeholder in public health assessments. Community groups and public health organizations do not always have the same resources to support meaningful participation in the public processes of IRIS. The EPA must not permit a privileged few to monopolize a process meant to foster open discussion.

Second, EPA should be diligent in developing firm "stopping rules," that guard against undue delay in releasing its assessments. Hundreds of new chemicals are released onto the market every year with no requirement that their safety be demonstrated. IRIS was created to address this lack of information on the potential toxicity of these chemicals and their influence on human health.

Unfortunately, the pace at which IRIS finalizes its assessments has slowed to an unacceptable rate. It is time EPA moves ahead with urgency to bridge this gap and fulfill its mission. I am looking forward to hearing from Dr. Olden on this matter.

It is clear that IRIS provides a valuable service to the American people. We must encourage EPA to be diligent in its efforts for continued improvement, and support them as they implement the recommendations of the National Academies.

Thank you, and I yield back.

